State of California Department of Public Health

Clinical Laboratory Registration

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a registration authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

UNIVERSITY OF SOUTHERN CA SCHOOL OF PHARMACY/MOBIL UNIT
1985 ZONAL AVE
LOS ANGELES CA 90033

OWNER(S):
USC SCHOOL OF PHARMACY

DIRECTOR(S):
BRIAN PRESTWICH MD

Lab ID Number: CLR 00328302
Effective Date: March 13, 2013
Valid Until: March 12, 2014
CLIA Number: 05D0989993

Beatrice R. O'Keefe, Division Chief
Laboratory Field Services

Policy CLIA		
EFFECTIVE DATE Aug 2009	DATE REPLACES 1-30-2005	PAGE 1 OF 54

SUBJECT and SCOPE
Mobile CLIA Waived Testing

Authority

Jeffery A. Goad, Pharm.D., MPH — Lic# 47375
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CLIA Waived Laboratory Director

Certified Laboratory Technologist — Lic# MTA36981

The USC School of Pharmacy is committed to providing the highest quality patient care services. USC pharmacists and intern pharmacists, under the supervision of said pharmacists, according to and in compliance with Article 3 of the B&P code 4052(a)(4)(C) and B&P code 4052 (a)(5)(A)(ii) of the California Pharmacy Scope of Practice section will provide non-diagnostic lipid panel and diabetes screening for a fee. All individuals who request to receive a screening will be provided with this service at the USC Campus Pharmacies or at a suitable location in compliance with the USC School of Pharmacy Mobile CLIA license (#05D0989993) in accordance with this policy and procedures, and any applicable federal and state law. All individuals who will receive the lipid panel or diabetes screening will sign a consent form and the USC School of Pharmacy will maintain a patient record of administration including, but not limited to, patient name, date, type of screening, and signature of the person providing the screening. All supplies needed for the screening as described in the procedures will be available and not expired. The laboratory director and consultant laboratory technician will be provided with periodic reports at their request of patients screened and referred using the risk assessment algorithm for lipids (appendix H) and diabetes patient assessment form (appendix O). Training of all pharmacists and intern pharmacists is comprehensive, competency based and integrated in the USC School of Pharmacy curriculum. It includes, but is not limited to, blood- borne pathogens and universal precautions, finger stick technique, emergency management, screening guidelines, and instrument specific training. By signing above, our CLIA waived laboratory director attests to the competency to perform blood glucose and lipid testing of those who have completed our standardized training program at the USC School of Pharmacy. In addition, our laboratory technologist attests to the accuracy of the following procedures for CLIA waived testing.

PROCEDURES

A. TESTING PROCEDURES

1. HEADING
   a. Organization: USC Campus Pharmacy and USC School of Pharmacy Mobile Unit
   b. Tests:
      (1) Blood glucose screening [REFER TO SECTION 1]
      (2) Cholesterol screening [REFER TO SECTION 2]

SECTION 1: BLOOD GLUCOSE SCREENING

2. PRINCIPLE
   a. Test Reaction Taking Place
      i. The OneTouch Ultra Glucose Meter measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement. When glucose is applied to the test strip, it is oxidized to gluconolactone via its reaction with glucose dehydrogenase (GDH) in the presence of a proprietary electron-transfer mediator. The reaction proceeds as follows:

$$2\ \text{mediator (oxidized)} + \text{glucose} \xrightarrow{\text{GDH}} 2\ \text{mediator (reduced)} + \text{gluconolactone}$$

   b. Clinical Application
      i. Glucose is the major energy source for the human body and is necessary for the growth, development and maintenance of virtually all cells in the tissues and organs. Blood glucose levels are maintained within a relatively narrow range. Insulin is the principal hormone that regulates glucose and any defect in the production or action of insulin can lead to diabetes mellitus. Patients with diabetes mellitus may develop various complications and some studies have shown that careful control of blood glucose levels may reduce the incidence or delay the onset of these complications.
3. SPECIMEN REQUIREMENTS
      i. OneTouch Ultra glucose meter requires a1 microliter (μL) blood sample from a finger stick or from the arm. The blood sample will be collected and applied to the OneTouch Ultra Test strip that is specific for the glucose meter. Blood from the fingerstick should flow freely. If fasting levels are to be obtained, the patient should not eat or drink anything other than water for 8 to 12 hours prior to the test.
4. REAGENTS

i. No reagents are needed to perform a blood glucose or cholesterol test. [Please refer to Quality Control section (A8) for information on materials used for quality control.]

5. EQUIPMENT

i. OneTouch Ultra includes: meter, logbook, owner's booklet / quick reference guide, OneTouch UltraSoft Blood Sampler, control solution, 3.0V lithium battery, and carrying case.

a. The meter can be used to measure glucose levels from different areas of the body including the fingertips and arm. The meter should be used in a location with a temperature between 43-111ºF (6-44ºC) and relative humidity 10-90%, a stable work surface, no direct heat (oven or room heater), and no bright light (sunlight or spotlight).

b. Test strips should be stored in their original container in a cool, dry place below 86ºF (30ºC). Keep away from direct sunlight and heat. Do not refrigerate. Do not use test strips beyond the expiration date printed on the package since it may cause inaccurate results. Discard test strips after 3 months from the date a new vial of test strips is opened. Replace the vial cap immediately after removing a test strip. Do not bend, cut, or modify test strips. Test strips are for single use only (never reuse).

c. No maintenance is required other than routine cleaning when necessary. If the surface of the meter becomes dirty, clean it with a damp, non-abrasive cloth. Most spills and stains will be removed with water or a mild detergent. A solution of 70% isopropyl alcohol is an appropriate cleaning agent. Do not immerse the instrument in water or other cleaning fluid, and do not spray any solution directly onto the meter. Do not attempt to clean the test port. When not in use, store the meter in the carrying case.

6. PROCEDURE

i. OneTouch Ultra Glucose Meter (Gloves should be worn whenever working with blood or samples that are potentially biohazardous.)

a. Prior to performing a test, all patients must sign a consent form (Appendix O). No assessment of any kind will be made on pregnant women or persons under the age of 18. Each patient must complete the "American Diabetes Risk Assessment" Form (Appendix P). For each patient, a "Participant Assessment Form" is used to record individual results and risk assessment scores (Appendix Q).

b. Clean the site chosen for the test (fingertip or arm) with warm soapy water or an alcohol swab and dry thoroughly.

c. Check the vial expiration date before placing the any strip into the meter. The meter will automatically be activated once a test strip is inserted.

d. Before lancing the finger, match the code numbers on the meter and the number on the vial of the test strips. If the code does not match, refer to the Owner's Manual for instructions on coding the meter.
e. Use a new single use, disposable lancet to perform the fingerstick each time a test is done.
f. Gently massage and warm the hand or arm to bring fresh blood to the surface. Refer to section B: Procedure drawing blood for information on how to lance the finger.
g. When the prompt to apply the sample appears on the screen (picture of a drop of blood), lance the finger and obtain an adequate amount of blood.
h. Gently touch only the edge of the test strip to the blood sample. A sample must be applied within 2 minutes after inserting the test strip. The test strip will then automatically draw the blood into the meter via capillary action. (If an error message appears, refer to the User's Manual.)
i. If an adequate sample was applied results will be displayed in 5 seconds. Record the results on the appropriate form.
j. Dispose everything that came into direct contact with the blood sample or control material into a biohazardous waste container.

7. CALCULATIONS: Test results will be displayed on the screen and no additional calculations are necessary.

8. QUALITY CONTROL

i. OneTouch Ultra

a. The OneTouch Ultra control solution is used to check that the meter and test strips are working together as a system and the test is performed correctly.
b. Check the expiration date on the control solution vial. Once opened, the control solution expires three months from the date the vial is first used (discard date). Do not use after the expiration date or discard date, whichever comes first.
c. The control solution should be kept at room temperature (68-77ºF/20-25ºC) before testing. Store control solution tightly closed at temperatures below 86ºF (30ºC). Do not refrigerate.
d. Shake the vial, discard the first drop of control solution, and wipe off the tip to ensure a good sample and an accurate result. Insert a test strip into the meter. Apply a drop of control solution to the edge of test strip and wait for results. The results should fall within the expected range printed on the test strip vial. If the results are outside this range, repeat the test with a new test strip. Results that fall outside the range may be due to:
    1. Error in performing the test.
    2. An expired or contaminated control solution.

3. Expired or deteriorated test strips.
4. Improper coding of the meter.
5. Meter malfunction.
6. Or control solution test performed outside proper temperature.

e. Contact the Customer care agency for further assistance if retest results are still not within the acceptable range. LifeScan 1-800-227-8562 or www.LifeScan.com.

f. The control solution test should be performed:
1. Once each day before patient samples are tested.
2. Whenever using a new vial of test strips.
3. When the meter is used for the first time, before doing a blood test.
4. Whenever the meter or test strips are suspected to be improperly working.
5. If the blood glucose test results are not consistent with patient's signs and symptoms.
6. If the meter is dropped, damage, or exposed to liquids.

9. INTERPRETATION

i. Blood glucose screening

a. Results from blood glucose readings and assessments will be based on guidelines from the American Diabetes Association (ADA).

Normal	**IFG or IGT ("Pre-Diabetes")**	**Diabetes Mellitus***
FPG < 100 mg/dL 2-h PG< 140 mg/dL	FPG ≥ 100 - 125 mg/dL (IFG) 2-h PG# ≥ 140 – 199 mg/dL (IGT)	FPG ≥ 126 mg/dL 2-4 PG ≥ 200 mg/dL Symptoms of DM and RPG concentration ≥ 200 mg/dL
*A diagnosis of diabetes mellitus must be confirmed on a subsequent day by measurement of FPG 2-h PG or RPG if symptoms are present. The FPG test is greatly preferred because of ease of administration, convenience, acceptability to patients, and lower cost. Fasting is defined as no caloric intake for at least 8 h. # This test requires the use of glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. *FPG=Fasting plasma glucose, PG=Post-prandial glucose, IFG=Impaired fasting glucose, IGT=Impaired glucose tolerance, RPG=Random plasma glucose, DM=Diabetes Mellitus*		

10. LIMITATIONS OF METHOD

i. Blood glucose screening

a. The measuring range for blood glucose is 20-600mg/dL (1.1-33.3 mmol/L). Results out of this range may not be accurate.

b. Hematocrit (Hct) range of 30-55% is needed to measure blood glucose. Hematocrit readings outside this range may produce inaccurate blood glucose results.

11. REFERENCES

a. American Diabetes Association: Standards of Medical Care in Diabetes (Position Statement). *Diabetes Care* 2005, 28:S4-36.
b. American Diabetes Associate: Diagnosis and Classification of Diabetes Mellitus (Position Statement). *Diabetes Care* 2005, 28: S37-42.
c. OneTouch Ultra System Owner's Booklet. 2002: LifeScan, Inc.
d. University of Southern California, Environmental Health and Safety Policies, Safety Policy #16: Bloodborne Pathogens. March 15, 2004 available at: http://policies.usc.edu/policies/safety060108.pdf
e. University of Southern California, Environmental Health and Safety Policies, Safety Policy #007: Hazardous Waste Management. March 15, 2004 available at: http://policies.usc.edu/policies/safety060108.pdf

12. SIGNATURES: Please refer to page 1 of Policy and Procedure Manual.

B. PROCEDURE FOR DRAWING BLOOD

1. Fingerstick Procedure for blood glucose screening
   a. A warm hand and good blood flow from the puncture site are essential in order to collect a good capillary sample. Gloves should be worn when working with blood samples and should always be changed between each patient.
   b. Insert a test strip into the glucose meter.
   c. Choose a spot that is on the side of one of the center fingers of either hand. To help increase blood flow, the fingers and hands should be warm to the touch. To warm the hand, you can:
      i. Wash the patient's hand with warm water, or
      ii. Apply a warm (not hot) compress to the hand for several minutes, or
      iii. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.

   d. Clean the site with an alcohol swab. Dry thoroughly with a gauze pad before pricking the finger or lancing the arm. Firmly prick the selected site with a lancet.

   e. Touch one edge of the test strip to the drop of blood without touching the skin. The test strip will automatically draw up the drop of blood through capillary action. If it necessary to collect another drop of blood, wipe the site with gauze then massage again from the base to tip until another drop of blood forms.

f. Wipe off any excess blood and have the patient apply pressure to the puncture until the bleeding stops.
g. Apply a band-aid to the puncture site.

SECTION 2: CHOLESTEROL SCREENING

2. PRINCIPLE
   a. Test Reaction Taking Place
      i. The Cholestech LDX System and CardioChek Analyzer use reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in blood. The Analyzers measure color changes of the four reagent pads. The amount of color formed is converted by the Analyzer to mg/dL, mmol/L or U/L (depending on the cassette used) and the results are shown on the liquid crystal display (LCD) screen.

      The CardioChek test system consists of three main parts. These include analyzer, Polymer Technology Systems (PTS) Panels Test Strips and a MEMo Chip. When a blood sample is applied to the Test Strip, a chemical reaction occurs producing a color change. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo chip. The analyzer converts this color reading into a test result, that is displayed on the screen.

      The Cholestech LDX System combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides and glucose. The sample is applied to a Cholestech LDX cassette, and the cassette is placed into the Analyzer where the plasma is separated from the blood cells. A portion of the plasma flows to the left side of the cassette where the low density lipoproteins (LDL and VLDL) are precipitated with dextran sulfate (50,000MW) and magnesium acetate precipitating reagent. The filtrate, containing both glucose and HDL cholesterol, is transferred to both reaction pads.

      The enzymatic reactions that occur when using CardioChek and Cholestech LDX System to measure cholesterol and HDL are listed below.

$$\text{Cholesterol esters} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Free Cholesterol} + \text{Fatty acids}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol oxidase}} \text{Cholest-4-ene-3-one} + H_2O_2$$

$$2\ H_2O_2 + \text{4-aminoantipyrine} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4\ H_2O$$

(TOOS: N-Ethyl-N-sulfonydroxypropyl-m-toluidine, sodium salt)

The CardioChek and Cholestech LDX Analyzers measure triglycerides by an enzymatic method based on the hydrolysis of triglycerides by cholesterol esterase to glycerol and free fatty acids.

$$\text{Triglycerides} + H_2O \xrightarrow{\text{Cholesterol esterase}} \text{Glycerol} + \text{Free fatty acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{\text{Glycerol Kinase, } Mg^{2+}} \text{Glycerol-3-phosphate} + \text{ADP}$$

$$\text{Glycerol-3-phosphate} + O2 \xrightarrow[\text{Oxidase}]{\text{Glycerol phosphate}} \text{Dihyroxyacetone phosphate} + H_2O_2$$

$$2\ H_2O_2 + \text{4-Aminoanipyrine} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 4\ H_2O$$

b. Clinical Application

i. Studies have shown that cholesterol plays an important role in coronary heart disease and that lowering cholesterol (total cholesterol, LDL, and triglycerides) significantly reduces the risk of developing heart disease. Studies have also shown that increases in HDL cholesterol are associated with additional reduction in coronary heart disease risk. Total cholesterol, HDL cholesterol and triglyceride levels are used in the calculation of an estimated LDL cholesterol value.

3. SPECIMEN REQUIREMENTS

i. CardioChek and Cholestech LDX Analyzers require 35-60 microliters (μL) blood sample from a finger stick. The sample will be collected using a capillary tube with plunger. The capillary tube should be completely filled in under 10 seconds to ensure proper mixing of blood and anticoagulant, to prevent clotting. The blood should be dispensed from the capillary tube within five minutes of collection, after which time the blood will begin to clot in the capillary tube. Blood from the finger stick should flow freely. Too much squeezing of the finger may cause inaccurate test results. (For details on the finger stick procedure, refer to Section B: Procedure for Drawing Blood.) If fasting levels are to be obtained, the patient should not eat for 9 to 12 hours prior to the test.

4. REAGENTS

i. No reagents are needed to perform a blood glucose or cholesterol test. [Please refer to Quality Control section (A8) for information on materials used for quality control.]

5. EQUIPMENT

i. The CardioChek Test System includes: CardioChek Analyzer, PTS Panels Test Strips, MEMo Chip, 2AAA 1.5 volt alkaline batteries, user manual, capillary tubes, capillary plungers, lancets,

Mini-Pet pipette, and/or pipette tips. No calibration of the Analyzer is done by the user. The information is on the MEMo Chip per Test Strip lot.

a. The CardioChek Analyzer should be used in a location that has a temperature between 20°C to 25°C (68°F to 77°F), a stable work surface, no direct heat (oven or room heater) and no bright light (sunlight or a spot light). If room temperature falls below 18°C, allow the analyzer to warm up at least 30 minutes to 1 hour before testing.
b. Each package of PTS Panels Test Strips contains color-coded MEMo Chip. The color coded MEMo Chip contains settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number. The MEMo Chip reads the test strip expiration date, tells the analyzer which test to run, contains the calibration curve and the lot number for the specific Test Strip Lot, controls test sequences and timing, and established the measuring range for the test. The MEMo Chip contains the proper settings for the corresponding Test Strip lot. The MEMo Chip must be in place to run a test. Only the MEMo Chip that is included with each package of strips should be used. The lot number code on the Test Strip vial, MEMo Chip, and analyzer must match. If the expiration date in the MEMo Chip has expired, the analyzer will display EXPIRED LOT. Test strip package should be stored in a cool, dry place at room temperature (20-30°C, 68°-86°F). Strips may be stored in a refrigerator (35-46°C, 2°-8°F), but must be brought to room temperature before using. Do not freeze. Test strip package should be kept away from heat and direct sunlight. Dessicant packet in the vial should not be removed. The cap should be replaced immediately after removing a test strip and the test strip should be used as soon as it has been removed from the vial. MEMo Chip should be kept either in the analyzer or stored with the original lot of strips. Store the test strips in the original vial. Do not combine with other strips and do not store the MEMo Chip in the test strip vial. After opening the test strips are stable until the expiration date if vial is properly stored and always capped.
c. The analyzer will give an indication on the display that the batteries need to be changed. When the display reads CHANGE BATTERY, no more tests can be run until the batteries are changed. Always replace batteries with high quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the test strip as soon as the result is displayed. The time/date and results in memory will not be erased when the batteries are changed. Dispose of old batteries properly!

d. No maintenance is required other than routine cleaning if necessary. If the exterior of the CardioChek analyzer needs cleaning, dampen a cloth with water and wipe the surfaces and the display area carefully. Do not use bleach, window cleaner, or hydrogen peroxide. A solution of 70% isopropyl alcohol is an appropriate cleaning agent. Be careful not to get the Test Strip Insert Opening wet. Carefully wipe he Test Strip Insert Opening with a clean, damp (not wet), lint-free tissue or cloth. Make sure the glass is very clean with no dust or fingerprints. The glass must be completely dry before running a test.

ii. The Cholestech LDX System includes: Cholestech LDX Analyzer, power supply, optics check cassette, test cassettes, user manual, procedure manual, capillary tubes, capillary plungers, lancets, Mini-Pet pipette, pipette tips, and printer and cable assembly. No calibration of the Analyzer is done by the user. Test information is on the brown, magnetic stripe of the cassette. The brown stripe is read by the Cholestech LDX each time a cassette is run.

a. The Cholestech LDX System should be used in a location that has a temperature between 20°C to 35°C (68°F to 95°F), a stable work surface, no direct heat (oven or room heater) and no bright light (sunlight or a spot light). If the temperature or light requirements are not acceptable, the Analyzer will shut down until they are met.

b. Each test cassette has two parts: the main body and the reaction bar. The main body contains a sample well where the blood sample is dispensed, and a brown, magnetic stripe. The magnetic stripe contains the test names, instructions to the Analyzer for running the tests on the cassette, and calibration information for converting the color reading to analyte concentration. The reaction bar holds the reagent pads, which contain the chemicals for each test. The test cassettes must be stored in the sealed foil pouches. Cassettes may be used until the date printed on the pouch when stored in a refrigerator (2°-8°C, 36°-46°F) or may be stored for up to 30 days at room temperature (less than 30°C, 86°F). Once cassettes have been stored at room temperature, they should not be returned to the refrigerator. Additionally, a cassette should not be used beyond the printed expiration date or if it has been stored at room temperature for more than 30 days. Cassettes should not be reused and should sit at room temperature for 10 minutes before opening the pouch. Use the cassette as soon as the pouch is opened.

c. No maintenance is required other than routine cleaning if necessary. Clean the outside of the Cholestech LDX Analyzer case with a clean, damp, non-abrasive cloth. Most spills and

stains will be removed with water or a mild detergent. A solution of 70% isopropyl alcohol is an appropriate cleaning agent. Do not immerse the instrument in water or other cleaning fluid. Do not use any abrasive cleanser. When necessary, clean the cassette holder tray with a cotton swab moistened with water or a 70% isopropyl alcohol solution. Dry with a second cotton swab.

6. PROCEDURE
    i. CardioChek Analyzer (Gloves should be worn whenever working with blood or samples that are potentially biohazardous.)
        a. Prior to performing a test, all patients must sign a consent form (Appendix A). No assessment of any kind will be made on pregnant women or persons under the age of 18.
        b. Run the Quality Control, if needed, as delineated in the Quality Control section.
        c. Insert correct MEMo Chip for the lot of strips in use.
        d. Insert MEMo Chip with finger notch (top) side up, lot number code facing down.
        e. Press either button to turn CardioChek ON. Analyzer will display lot code. Make sure that the code matches the one on the test strip vial.
        f. When INSERT STRIP is displayed, insert the strip into the Test Strip Insert Opening as far as it will go.
        g. Obtain a blood drop following a correct technique. Please refer to Section B for Procedures for Drawing Blood.
        h. When APPLY SAMPLE is displayed, apply blood to the Test Strip with a capillary tube. Fingerstick samples must be applied within five minutes after collection or the blood will clot.
        i. Within one to two minutes, the results will be displayed. Record the results on the appropriate form. (Appendices I-L)
        j. If there is a problem with the test, a message will appear on the screen. See the “Troubleshooting and Maintenance” section for further instructions if any problems occur. (Appendix N)
        k. Remove test strip and discard. Put everything that came into direct contact with the blood sample into a biohazardous waste container.
        l. The analyzer automatically shuts down after three minutes of idle time with no Test Strip inserted. DO NOT leave a used Test Strip or Check Strip in the analyzer Test Strip Opening. This prevents the analyzer from automatically shutting down and shortens battery life.
        m. Test results are automatically stored in the analyzer’s memory. CardioChek can store up to 30 results of each chemistry and at least 10 results of each control test. The analyzer allows review of the results in order from the most recent to the oldest. Each

result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

n. To review results stored in memory turn the analyzer ON by pressing either button. If the display reads INSTALL MEMO CHIP go to the next step. If the display reads INSERT STRIP press Enter.
o. Press Next until MEMORY is displayed.
p. Press Enter and CHEM will be displayed.
q. Press Enter, then Next to select the desired chemistry.
r. Press Enter to view the test result including time and date.
    a. To recall Control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROL is displayed.
    b. Press Enter when the desired Control test is displayed.
    c. For example, to review Lipid Panel results, from the CHEM display, press NEXT until LIPIDS is displayed, then ENTER. The time and date will be displayed. Press ENTER when the desired test time and date is displayed. Press NEXT to scroll through the results.
s. To clear results stored in memory press either button to turn analyzer ON. Wait for the display to read either INSTALL MEMO CHIP or INSERT STRIP.
t. Press Enter, then press Next until UTILITY is displayed. Press Enter.
u. Press Next until CLEAR MEMORY is displayed. Press Enter.
v. Press Next until the display reads CLR YES. Press Enter. The display will read ERASE, CLEARED, and then CLEAR MEMORY.
w. To exit, press Enter until the display reads EXIT, then press Enter. Press Next until you return to RUN TEST.

ii. Cholestech LDX (Gloves should be worn whenever working with blood or samples that are potentially biohazardous.)

a. Prior to performing a test, all patients must sign a consent form (Appendix A). No assessment of any kind will be made on pregnant women or persons under the age of 18.
b. If the cassette has been refrigerated, allow it to come to room temperature (at least ten minutes) before opening.
c. Make sure the Analyzer is plugged in and has warmed up.
d. Run Optics Check and/or Quality Control as delineated on page 5, section (A)(6) Quality Control.
e. Remove the cassette from its pouch. Hold the cassette by the short sides only. Do not touch the black bar or the brown magnetic stripe. Place the cassette on a flat surface.
f. Press RUN. The Analyzer will do a self-test. The screen will display:

Selftest running

Testing memory

g. Then a message on the screen will appear:

Selftest OK

h. The cassette drawer will open. The screen will read:

Load Cassette

i. Depending on sample type, use the Cholestech LDX capillary tube (fingerstick) or Mini-Pet pipette (control material) to place sample into the test cassette sample well. Fingerstick samples must be applied within five minutes after collection or the blood will clot.

j. If the cassettes have been refrigerated, allow them to come to room temperature for at least 10 minutes before opening. Hold the cassettes by the short sides only. Do not touch the black bar or the brown magnetic stripe. Keep the cassette level after the sample has been applied. Immediately place the cassette into the drawer of the Analyzer. The black reaction bar must face toward the Analyzer. The brown magnetic stripe must be on the right.

k. Press <u>RUN.</u> The drawer will close. During the test, the screen will display:

[Test Name(s)] Running****

l. Put everything that came into direct contact with the blood sample or control material into a biohazardous waste container.

m. When the test is complete, the Analyzer will beep. The screen will display:

[Test Name(s)]=### units/date/warnings

n. Press DATA to view the calculated results.

o. When results are outside the measuring range of the test the screen will display:

[Test Name] >### or [Test Name] <###

p. If there is a problem with the test, a message will appear on the screen. See the "Troubleshooting and Maintenance" section for further instructions if any problems occur. (Appendix N)
q. When the drawer opens, remove the cassette. Put it in a biohazardous waste container. Leave the Analyzer drawer empty when not in use.
r. Record the results on the appropriate form. (Appendices I-L)

7. CALCULATIONS: Test results will be displayed on the screen and no additional calculations are necessary.
8. QUALITY CONTROL
   i. CardioChek
      a. Quality control on CardioChek should be performed with each new Test Strip lot or whenever there are questions about the results.
      b. To perform a quality control test the following will be needed: CardioChek Analyzer, PTS PANELS Test Strips, Quality Control Materials provided by PTS such as PTS PANELS Multi-Chemistry Controls and PTS PANELS HDL Controls, Quality Control Instructions, and Quality Control Range Insert.
      c. Do not use control solutions that have expired. Check the expiration date printed on the control bottles.
      d. Install correct MEMo Chip for the lot of strips that are being used.
      e. Press either button to turn the analyzer ON.
      f. Press Next until the display reads UTILITY. Press Enter.
      g. Press Next until RUN CONTROL is displayed. Press Enter.
      h. Insert the test strip into the analyzer. The CardioChek will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied.
         a. Immediately replace vial cap, making sure the strip vial is closed tightly.
      i. Remove cap from the Control Material and turn bottle upside down.
         a. CONTROL MUST BE APPLIED TO THE TEST STRIP WITHIN 10 SECONDS OF REMOVING THE STRIP FROM THE VIAL.
      j. Hold bottle directly over and perpendicular to the blood application window of the Test Strip.
      k. Squeeze bottle, so a small drop of solution is formed.
      l. Allow the drop of control solution to fall onto the application window of the Test Strip. Do not allow the tip of the bottle to touch the Test Strip.
      m. Replace cap on the Control Material.
      n. Results will be displayed within about one to two minutes.
      o. Compare control results to the values on the Quality Control Range Insert included with control materials.

p. The control result(s) will also be stored in the analyzer's Memory.
q. To exit the control testing menu press Enter twice. RUN CONTROL will be displayed.
r. Press Next until EXIT is displayed. Press Enter.
s. Press Next until RUN TEST is displayed.
t. If Quality Control Results are in Range, continue testing patient samples.
u. If Quality Control Results are not in Range do not use the Analyzer for testing patient samples until the problem is resolved. The following may be tried:
    a. Ensure Test Strip insert opening area is clean.
    b. Make sure neither the Test Strips nor the controls are past the expiration date printed on the label.
    c. Make sure MEMo Chip matches the lot.
    d. Repeat the test again using fresh materials.
    e. Call CardioChek PTS Customer Service for assistance at 1-877-870-5610 (Toll-free inside the United States) or 1-317-870-5610.
v. A gray Instrument Check Strip (included in the analyzer carrying case) can be used to verify proper functioning of the CardioChek's electronic and optical systems. The Instrument Check Strip provides a color standard read by the analyzer. When the Check Strip in not in use, it should be stored in the analyzer carrying case. It is recommended that the analyzer be checked with the Instrument Check Strip when the analyzer is first received, if the analyzer is dropped, or when a result that is not expected is obtained. To check the analyzer the follow the steps below:
    a. Turn the analyzer ON by pressing either button.
    b. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
    c. Press Enter when CK STRIP is displayed.
    d. Insert the Check Strip, ribbed side up, into the Test Strip Insert opening when INSERT STRIP is displayed.
    e. The analyzer should display PASSED.
        i. Remove the Check Strip and store it in the analyzer carrying case.
        ii. Press Next until EXIT is displayed. Press Enter.
        iii. Press Next until RUN TEST is displayed.
        iv. Press Enter. The analyzer is ready to run tests.
    f. If the analyzer displays FAILED
        i. Clean the CardioChek Test Strip Insert Opening (where the strip is inserted into the analyzer)

with a soft, lint-free, damp cloth. See Storage and Handling section under EQUIPMENT.

ii. Inspect the Check Strip to make sure it is not dirty or damaged. Use the spare Check Strip and repeat.

iii. See Troubleshooting section. (Appendix N)

ii. Cholestech LDX

a. A Cholestech LDX Optics Check Cassette with known reflectance values is supplied with each Analyzer. It should be used to check the optical system of the Analyzer. The Cholestech LDX Optics Check Cassette should be stored at room temperature in the case provided. The reaction bar should not be touched or allowed to become wet, dirty or scratched. A damaged or expired Cholestech LDX Optics Check Cassette should not be used. The Cholestech Optics Check Cassette should be run once each day before patient samples are tested and anytime after the Analyzer has been moved or serviced.

b. The Optics Check Cassette test procedure is as follows: After verifying the "Self Test OK" message, press the RUN button. The drawer will open, and the screen will display:

Load cassette And press RUN

c. Place the Optics Check Cassette into the cassette drawer. Do not place any blood sample on the cassette.

d. Press the RUN button again and the Analyzer will automatically perform the Optics Check. The words Optics Check and four numbers will appear on the screen, one for each optical channel in the Analyzer.

Optics Check ##-##-##-## Ch#1-Ch#2-Ch#3-CH#4

e. If the numbers for all four channels fall within the ranges printed on the Optics Check Cassette label, the system is ready for use.

f. If the numbers for any of the four channels fall outside the ranges printed on the optics check cassette label the Analyzer will shut down. Try running an optics check with a different Optics Check Cassette. If the numbers are still outside the range, call Cholestech Technical Service at 1-800-733-0404.

g. Record the results in the Optics Check Log each day. (Appendix E)

h. Specific quality control materials should be provided for at least two levels of total cholesterol, HDL cholesterol and triglycerides. The preferred quality control material for use with the Cholestech LDX System is Cholestech LDX Level 1 and Level 2 control materials. The expiration date should be checked before use. Control material should not be used beyond the expiration date. The quality control material should be mixed by gentle inversion 7-8 times before use. Follow the same test procedures used for a fingerstick blood sample, with the exception that a Mini-Pet pipette should be used to apply the control sample to the test cassette in lieu of a capillary tube.

i. A high and a low control for each analyte are preferred. The results should be within range before testing patient samples. Quality control material should be tested on each new shipment of cassettes, on each lot of cassettes received, and if you think the cassettes may not have been stored properly and recorded on the Quality Control Log (Appendix E). Results for Cholestech controls should be within the ranges included with the control. The expected ranges for each lot of controls are calculated using several LDX Analyzers and test cassette lots. If results for all analytes are within the expected ranges, patient samples may be tested and the results reported. If results of one or both levels of control tested are outside the established ranges:
    1. Check that the expiration date for the test cassette and quality control materials have not passed.
    2. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
    3. If the control is within acceptable limits, patient samples may be tested and results reported.
    4. If the control is outside the acceptable limits, retest with a sample of control from a new vial.
    5. If results are in range, continue testing patient samples. However, if the control is still outside the acceptable limits, contact Cholestech Technical Service at 1-800-733-0404. Do not use the Analyzer for testing patient samples until the problem is resolved.

j. Temperature charts will be maintained on a daily basis for both the refrigerator temperature and the room temperature. Acceptable refrigerator temperatures for storing cassettes and control solutions will be 2°-8° C (36°-46° F). If a temperature is read outside this range, the materials will be moved to another refrigerator within the acceptable

temperature range immediately. Acceptable room temperature for the machine is 68°-95° F. However, for the cassettes kept at room temperature, the maximum threshold is less than 86° F. Therefore, the acceptable room temperature range will be 68°-86° F.

9. INTERPRETATION

i. Cholesterol screening

a. Total Cholesterol: The National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP III) of the National Heart, Lung and Blood Institute (NHLBI) has recommended the following guidelines for total cholesterol in adults:

Desirable: Less than 200 mg/dL
Borderline High: 200-239 mg/dL
High: Equal to or greater than 240 mg/dL

b. HDL Cholesterol: The Adult Treatment Panel III (ATP III) recognizes that an HDL cholesterol level below 40 mg/dL is associated with risk of coronary heart disease (CHD) in men and women. A desirable HDL cholesterol level is greater than 40 mg/dL. HDL level greater than 60 mg/dL decreases CHD risk. Studies have shown an inverse relationship between HDL cholesterol levels and the incidence of CHD.

c. Triglyceride: The ATP III of the NHLBI has recommended these guidelines for fasting triglyceride levels:

Normal: Less than 150 mg/dL
Borderline High: 150-199 mg/dL
High: 200-499 mg/dL
Very High: Equal to or greater than 500 mg/dL

d. LDL Cholesterol[2]: The ATP III of the NHLBI has recommended the following guidelines for LDL cholesterol:

Optimal: <100 mg/dL
Near Optimal: 100-129 mg/dL
Boarderline High: 130-159 mg/dL
High: 160-189 mg/dL
Very High: ≥ 190 mg/dL

- CHD and CHD risk equivalents*: Less than 100 mg/dL
- Multiple (2+) risk factors[#]: Less than 130 mg/dL
- 0-1 risk factor: Less than 160 mg/dL

**CHD Risk Equivalent: Diabetes*
#Risk Factors: Cigarette smoking, hypertension, low HDL cholesterol (<40 mg/dL), family history of premature CHD, age

e. TC/HDL Ratio: The TC/HDL ratio can be a useful summary of CHD risk. A ratio of 4.5 or less is desirable. A ratio greater than 6.0 means a high risk of CHD.

10. LIMITATIONS OF METHOD

i. Cholesterol screening

a. The measuring range for total cholesterol is 100-500 mg/dL. Results outside this range will appear as <100 mg/dL or >500 mg/dL.
b. The measuring range for HDL cholesterol is 15-100 mg/dL. Results outside this range will appear as <15 mg/dL or >100 mg/dL.
c. The measuring range for triglycerides is 45-650 mg/dL. Results outside this range will appear as <45 mg/dL or >650 mg/dL.
d. If the triglycerides are >400 mg/dL, the estimated LDL will not be calculated.
e. If the triglycerides are >650 mg/dL, the HDL result may not be accurate and will appear as N/A.
f. Patients' samples with total cholesterol, HDL cholesterol or triglyceride values outside the measuring range will be recommended to see a physician for follow-up.

11. REFERENCES

a. Cholestech LDX Procedure Manual. 1999: Cholestech Corporation.
b. CardioChek Analyzer Manual. http://www.quickmedical.com/Polymer/cardiochek_guide.html
c. Executive Summary of the Third Report of the National Cholesterol Education Program Education Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III), *JAMA* 285: 19 (2001).
d. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. *Circulation*. 2004; 110:227-239.
e. University of Southern California, Environmental Health and Safety Policies, Safety Policy #16: Bloodborne Pathogens. March 15, 2004 available at: http://policies.usc.edu/policies/safety031504.pdf
f. University of Southern California, Environmental Health and Safety Policies, Safety Policy #007: Hazardous Waste Management. March 15, 2004 available at: http://policies.usc.edu/policies/safety031504.pdf

12. SIGNATURES: Please refer to page 1 of Policy and Procedure Manual.

PROCEDURE FOR DRAWING BLOOD

1. Fingerstick Procedure for Cholestech LDX and CardioChek Analyzer
   a. A warm hand and good blood flow from the puncture site are essential in order to collect a good capillary sample. Gloves should be worn when working with blood samples and should always be changed between each patient.

b. Put a capillary plunger into the end of a capillary tube with the red mark. Set it aside.
c. Choose a spot that is on the side of one of the center fingers of either hand. To help increase blood flow, the fingers and hands should be warm to the touch. To warm the hand, you can:
    iv. Wash the patient's hand with warm water, or
    v. Apply a warm (not hot) compress to the hand for several minutes, or
    iii. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
d. Clean the site with an alcohol swab. Dry thoroughly with a gauze pad before pricking the finger.
e. Firmly prick the selected site with a lancet.
f. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood as it may contain tissue fluid.
g. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. Do not milk the finger. The puncture should provide a free-flowing drop of blood.
h. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action up to the black mark. Do not collect air bubbles. If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.
i. Wipe off any excess blood and have the patient apply pressure to the puncture until the bleeding stops.

C. PROCEUDRE FOR HANDLING AND DISPOSAL OF BIOLOGICAL MATERIAL

a. Lancet Disposal: Dispose lancets immediately after each use. Lancets are to be placed in red, puncture resistant sharps container marked with a biohazard symbol. Lancets are not to be disposed in wastebaskets or regular trash containers
b. Materials contaminated with blood: Items in contact with blood (e.g. cotton balls, gauze, band aids) are to be disposed of in red plastic bags marked with a biohazard symbol. They are not to be placed in red sharps containers with the lancets.
c. The University of Southern California Safety Policy #16: "Bloodborne Pathogens" and the University of Southern California, School of Pharmacy Campus Pharmacies Policy #2: "Blood Borne Pathogens Prevention Program" procedures will be used (Appendix C).
d. In accordance with the University of Southern California Safety Policy #007: "Hazardous Waste Management," Career and Protective Services will remove and dispose of waste appropriately. (Appendix S)

D. PROCEDURE TO BE EMPOLYED IN HANGLING EXCESSIVE BLEEDING, FAINTING, OR OTHER MEDICAL EMERGENCY

a. Bleeding
   i. Apply pressure over wound with wad of sterile gauze.
   ii. If bleeding continues and elevate wound until bleeding stops.
   iii. If bleeding still continues, apply pressure to blood vessels leading to area in arm, press just below armpit; in leg, press against groin where thigh and trunk join.
   iv. Use a tourniquet (tight band that cuts off circulation) only when it has been decided that the sacrifice of a limb is necessary to save life.

b. Fainting
   i. Keep the affected person lying flat or sitting forward with the head bent below the knees.
   ii. Loosen the patient's clothing is possible.
   iii. Cool the room down or move the person to a cooler location if heat is a problem (This can be especially helpful for someone with a history of heart problems as a cause of fainting).

c. Medical Emergency
   i. Call 911 immediately.

E. PROCEDURE FOR REPORTING ASSESSMENT RESULTS TO INIDIVIDUAL BEING ASSESSED AND REFERRAL TO THOSE WITH POSSIBLE RISK FACTORS OR MARKERS

a. Refer to Appendices I-L, O, Q

F. DOCUMENTATION SHOWING AUTHROIZATION OF SCREENING STAFF TO PERFORM SKIN PUNCTURES

a. Refer to Appendix T

G. DOCUMENTATION SHOWING STAFF HAVE BEEN TRAINED ACCORDING TO MANUFACTURER'S DIRECTIVES

a. Refer to Appendix T

H. SUPERVISORY COMMITTEE MEMBERS

a. California licensed physician: Roscoe Atkinson, MD
Assistant Professor of Clinical Pathology
Keck School of Medicine
(323) 442-2736

b. Clinical laboratory technologist: Jay Santa Ana
Director, Laboratory Services
USC University Hospital
Lic# MTA36981

c. California licensed pharmacist Jeffery A. Goad, Pharm.D., MPH
Associate Professor of Clinical Pharmacy, USC School of Pharmacy
(323) 442-1907

I. CLIA LABORTORY CERTIFICATE OF WAIVER

a. CLIA ID Number: 05D0989993
b. Expiration date: 08/09/2011 (Appendix U)

J. LIMITED QUANTITY HAULING EXEMPTION

a. Limited Quantity Medical Waste Transporter: Registration # 19-1436
Expires: December 17, 2006. (Appendix S)
b. Small Quantity Medical Waste Generator: Registration # 19-11323
Expires: December 17, 2006. (Appendix S)

K. Non-Diagnostic General Health Assessment (NGHA) – Appendix V

APPENDIX A – PATIENT CONSENT FORM
PARTICIPANT CONSENT FORM

USC School of Pharmacy
Cholesterol Screening

Patient's Name: _____

Today's Date: _____

Three Step Process:

1. A finger prick on the middle or ring finger with a lancet will be used to obtain the blood specimen.
2. The blood specimen will be taken up by a capillary tube, inserted into a cassette or placed onto a PTS PANELS Test Strip, and placed in the Cholestech LDX® or CardioChek analyzer respectively.
3. The machine will run and within 5 minutes, a blood cholesterol level for HDL, TG, Total Cholesterol, and calculated LDL will be obtained.

Have you consumed food or liquid other than water in the past 8 hours? ____Yes ____No
Are you currently on any cholesterol lowering medication? ____Yes ____No

Patient Address _____
_____
_____

Please initial below:

_____ I understand the risks and benefits of the results from a cholesterol screening.

_____ I authorize this pharmacy to release my evaluation and other information to other healthcare providers in order to ensure continuity of care. I would like this pharmacy to contact my physician with the results of the assessment.

If **YES**, please provide physician information:

Physician Name _____
Address _____
City/Zip _____
Phone _____

Patient Signature: _____

APPENDIX B

Follow these suggestions to help you consistently perform good fingersticks:

Suggestion	Reason
Perform a deep and firm puncture	An adequate puncture is crucial to obtaining a free flowing drop of blood
Keep the patient's hand below the level of their heart	This will improve the blood flow
Hold the capillary tube at a slight descending angle to the drop of blood	This will make the capillary tube fill faster
Fill the capillary in under 10 seconds	This will ensure proper mixing of blood and anticoagulant, which prevents clotting
Dispense blood from capillary tube in less than five minutes	After five minutes, the blood will begin to clot in the capillary tube
If blood stops flowing, wipe finger firmly with gauze	You can improve blood flow by reopening the puncture

WARNING: Squeezing the finger excessively may cause inaccurate test results.

APPENDIX C: BLOOD BORNE PATHOGENS EXPOSURE CONTROL PLAN

University of Southern California
Bloodborne Pathogens Program
Exposure Control Plan

PI/Supervisor Department___Jeff Goad/Pharmacy_____
Room Phone____323-442-1907_____

PROGRAM SCOPE

The University of Southern California (USC) Exposure Control Plan describes how to eliminate or minimize exposure of all USC personnel to human/non-human primate blood or blood products that might contain bloodborne pathogens. This Exposure Control Plan demonstrates compliance with the California OSHA Bloodborne Pathogens Standard (8CCR Sec. 5193) http://www.dir.ca.gov/title8/5193.html

RESPONSIBILITIES

Each Principal Investigator (PI) or Supervisor will:

1. **Print and review** the Exposure Control Plan based on the nature of the research or clinical activities being performed in their facilities. The plan shall be available to all personnel within the laboratory/work place along with the other relevant USC safety documents.
2. Determine which faculty, students and staff are subject to the provisions of the standard, using **Appendix 1**, **Exposure Determination**. Keep a copy of the Exposure Determination with the printed Exposure Control Plan.
3. Assure that these faculty, staff and students are referred to Laboratory Safety (http://capsnet.usc.edu/LabSafety/index.cfm) to register for **training** at the time of initial assignment and annually thereafter.
4. Offer each eligible faculty, staff or student the **Hepatitis B vaccine**. Each employee shall complete **Appendix 2, Hepatitis B Declaration Form**. For those that accept the offer, direct them to contact the designated health care facility for an appointment (see below). A copy of this form must be sent to Laboratory Safety. Additional directions can be found in Appendix 2.

PROGRAM COMPONENTS

Universal Precautions

8CCR Sec. 5193 defines universal precautions as an approach to infection control where all human/non-human primate blood and other body fluids, tissues and cells are treated as

if they were infectious for Human Immunodeficiency Virus, Hepatitis B, Hepatitis C, and other Bloodborne Pathogens (BBPs).

Exposure Determination

The Principal Investigator/Supervisor will determine which faculty, staff or students are involved in procedures that create a potential exposure to BBPs. These procedures include but are not limited to the following:

- Phlebotomy or venipuncture of humans or non-human primates
- Injections into humans or animals using non-human primate or human specimens
- Other use of needles with human or non-human primate specimens
- Pipetting, mixing, or handling human or non-human primate blood, fluid, or tissue
- Centrifuging human or non-human primate blood, fluid or tissue
- Handling human or non-human primate tissue, including preparation, dissection, cutting
- Handling tubes or other container of human or non-human primate blood, fluid, cultures or tissue
- Handling contaminated sharps or other contaminated waste
- Cleaning spills of human or non-human primate blood or other body fluids
- Other procedures or tasks that would create risk of exposure to BBPs

ALL classifications at risk for exposure include the following:

- All health care and allied services classifications
    - Hospital attendants
    - Technologists
    - Nurses
    - Physicians and dentists
    - Pharmacists
    - Medical auxiliary services
    - Radiation physicists
    - Medical assistants
    - USC Social services
    - College of Medicine Psychologists
    - USC Therapeutic services (physical therapists, occupational therapists)
    - USC facilities services
- Police
- Housekeeping
- Plumbers
- Environmental Health and Safety, Laboratory Safety staff

SOME Classifications at risk including:

- Faculty/principal investigator
- Senior or staff research associate
- Laboratory supervisor or assistant
- Veterinarian or animal health technician

- Others as defined by Principal Investigator/Supervisor

METHODS OF COMPLIANCE [5193(d) (i)]

Information and Training [5193(g)(2)]

All staff that have the potential for exposure to BBPs must have initial and annual training for bloodborne pathogens. To sign up for a training session, contact Laboratory Safety at (323) 442-2200 or visit their website, http://capsnet.usc.edu/LabSafety/index.cfm.

Written Exposure Control Plan [5193(c)(1)]

The Principal Investigator/Supervisor will print this laboratory specific plan and file it in the USC Hazardous Materials Management Program Binder in a central location within the laboratory for all personnel to access. The plan will be reviewed and revised annually or whenever significant changes in procedure or personnel occur. Additional copies of the uncompleted plan are available at the Laboratory Safety Department or on the web at http://capsnet.usc.edu/LabSafety/index.cfm.

Engineering and Work Practice Controls [5993 (d)(2)]

Engineering and work practice controls must be used to eliminate or minimize exposure to individuals. The following engineering and work practice controls will be utilized:

Personal Protective Equipment [5193(d)(3)]

Personal protective equipment (PPE) will be provided without cost to all individuals who are at risk of occupational exposure to bloodborne pathogens**.** All PPE will be inspected, cleaned, or replaced as needed at no cost to personnel. PPE will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the individual's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used. All PPE must be selected with the goal of providing protection from a hazard. Selection of alternate choices of PPE should be considered if the user is at risk of physiological discomfort (such as contact dermatitis from latex gloves or asthma from wearing certain face masks). Proper training on the wearing and function of personal protective equipment is required PRIOR to using PPE. Consultation or advice on PPE is provided by the University of Southern California Laboratory Safety Department.

Eye protection

Protective eyewear must be worn in the laboratory when it is reasonably anticipated that blood or other potentially infected material may make contact with the eye. Face shields may be required if there is a potential for splashes, sprays, or aerosols.

Lab coats and uniforms

Laboratory coats, gowns, or other protective clothing must be worn while in the laboratory; long sleeves are required. Before leaving the laboratory, this protective clothing must be removed and left at the work site. Sandals and open-toed shoes are not permitted. Personnel must wear additional PPE (apron, booties, face shield, etc.) that is required. All PPE will be removed prior to leaving the work areas and placed in designated areas for disinfection or disposal. Faculty, staff or students are not permitted to take PPE home to launder.

Gloves

All personnel engaged in activities that may involve skin contact with potentially infectious fluids or tissues must wear gloves. Gloves are also required for laboratory workers with skin conditions on the hands that may have direct or indirect contact with potentially infectious materials. Hand washing with soap and water must be a routine practice performed immediately after removal of gloves. Gloves should be removed before touching common equipment (phone, computer, appropriate laboratory equipment) to prevent the spread of contamination. Personnel must wear gloves, lab coat, and safety glasses whenever handling human or non-human primate blood, fluids, or tissue. Gloves must be replaced frequently and immediately if they become contaminated or damaged in any way.

Hand Washing

Personnel must wash their hands immediately upon removal of gloves and upon any contact with potential BBP materials.

Mouth Pipetting

Mouth pipetting is prohibited.

No Eating, Drinking, or Smoking

Eating, drinking, smoking, applying cosmetics or lip balm, and handling inhalers or contact lenses are not permitted in work areas. Food and drink are not to be placed or stored in areas (refrigerators, microwaves, etc.) where potential BBP are kept or may be present.

Needles, Sharps, and Broken Glass

Used needles and other sharps are not to be sheared, bent, broken, recapped, or resheathed by hand. Disposable sharps must not be reused. **All sharps, contaminated or not**, **will be disposed of in a puncture-resistant hard sided, labeled sharps container**.

The CAL-OSHA BBP Standard requires any laboratory using human or non-human primate blood, blood products, cell lines, tissues or other potentially infectious materials to use **needleless systems, non-needle sharps or engineered sharps**. Furthermore, USC procedures requires laboratories using needles with animals to implement needleless systems or engineered sharps controls. Needleless system means a device that does not use needles for (1) the withdrawal of body fluids; (2) administration of medication or fluids; and (3) performance of any other procedure involving the potential for an exposure incident. Engineered sharp means either (1) a physical attribute built into a needle device or (2) a physical mechanism that effectively reduces the risk of an exposure incident. **If the Principal Investigator/Supervisor decides that a non-compliant sharp is necessary for a certain procedure, the reason must be documented in Departmental files and on the Institutional Biosafety Committee protocol form.**

Any broken glassware must not be directly handled with a gloved or bare hand. Use of a mechanical tool (tongs, dustpan and broom) to collect the pieces into a hard-sided container labeled 'broken glass' is enforced. Contaminated broken glass must be placed in a puncture-resistant hard sided sharps container and disposed of as biohazardous waste.

Minimization of Aerosols

All procedures must be performed carefully to minimize the creation of aerosols. Biological safety cabinets (Class II or III) or other physical containment devices must be used whenever possible while performing operations capable of creating aerosols. These operations may include:

- Centrifugation
- Blending
- Homogenization
- Opening pressurized containers.

If a biological safety cabinet is not available, the most effective means of minimizing exposure is to use closed containers (centrifuge tubes, sealed centrifuge rotors, capped test tubes, etc.).

Disinfection of Work Area and Spill Cleanups

Blood and blood products will be handled in an area that can be readily decontaminated. The work area must be disinfected before and after handling microorganisms. Non-laboratory personnel should not handle equipment that has been used with potential BBPs until it has been decontaminated. All spills must be cleaned up immediately and disinfected with a germicide by appropriate decontamination procedures determined by the laboratory supervisor. The laboratory supervisor or other laboratory personnel must immediately report laboratory accidents to the Laboratory Safety Department at (323) 442-2200.

Labeling

A biohazard warning sign incorporating the universal biohazard symbol will be posted on the access door to the laboratory work area. All human tissue, body fluid, or other potentially infectious materials must be stored in a container labeled with a biohazard symbol. Equipment where BBPs or potentially infectious materials are stored or handled must also be labeled with the biohazard symbol. All signs are available from Laboratory Safety.

Transportation on Campus

Specimens of blood or other potentially infectious materials will be placed in a primary container that prevents leakage (capped test tube, centrifuge tube, etc.) during collection, handling, and storage. If the specimens are transported outside of the lab or work site, the primary containers must be placed in a secondary container (bucket, beaker, cooler, etc.) which would contain the contents if the primary container if it were to leak or break.

Shipping of Samples

Specimens of blood or other potentially infectious materials that will be shipped to or from University of Southern California must be clearly identified as human blood or blood products. The material will be placed in a closed primary container and a leak proof secondary container prior to shipment. Personnel involved with shipping of biohazardous agents or potential BBPs **must have** documented training prior to shipping. Contact Laboratory Safety (323) 442-2200 for additional information on training for shipping samples or specimens.

Biological Waste Disposal

Disposal of potentially hazardous biological materials will be performed with appropriate consideration for the personnel involved in the handling of laboratory waste, as well as federal, state and local laws concerning the disposal of such materials. In accordance with the California Medical Waste Management Act, Health and Safety Code, Chapter 6.1, medical waste includes but is not limited to:

- Human or animal specimens or infectious cultures

- Needles and syringes
- Cultures and stocks of infectious agents
- Wastes from the production of bacteria, viruses, or the use of spores, discarded live and
- attenuated vaccines, and cultures
- Waste which contains recognizable blood, fluid blood products, containers or equipment containing blood, or blood from animals known to be infected with diseases which are communicable to humans.

Specific procedures for the disposal of biological materials are available from Laboratory Safety (http://capsnet.usc.edu/LabSafety/index.cfm) and can also be found in the Hazardous Materials Management Program binder.

REPORTING AND TESTING

Reporting and Documenting Sharps Injuries

All sharps related injuries will be reported immediately by completing a University of Southern California, "Employers Report of Occupational Injury or Illness". They will notify Laboratory Safety who will initiate a review of the injury and enter the information into a Sharps Injury Log (within 14 days of the injury). The Sharps Injury Log is maintained for five years by Career and Protective Services. The Biological Safety Specialist and the Occupational Safety and Health Specialist will review the log to identify trends and take corrective action.

Medical Surveillance Program [5193(f)]

University of Southern California Laboratory Safety has made arrangements for all appropriate required medical services related to bloodborne pathogens.

Hepatitis B Vaccination

A safe and effective vaccine is available for protection from Hepatitis B. The University of Southern California encourages employees to be vaccinated. The employee may decline the vaccination. Accepting vaccination is not a condition of employment. This vaccine is available at no cost to the employee. Post-vaccination serological testing to assure that antibodies to hepatitis B have developed is also provided at no cost following completion of the vaccination series. The Principal Investigator/Supervisor will assure that all personnel with potential for occupational exposure to bloodborne pathogens are offered the Hepatitis B (HBV) vaccination as soon as possible. Students should be referred to Laboratory Safety for the appropriate forms.

If you decide not to be vaccinated but later change your mind, you may still receive the vaccination at no cost. Each employee who declines the HBV vaccination series is required to sign a declination form that will be filed in the

Principal Investigator/Supervisor Departmental records and with the Laboratory Safety Department.

Post-Exposure Evaluation and Follow-up [5193(f)(3)(A)]

Any exposure (e.g. spill, needlestick, ingestion) resulting in direct, unprotected contact with human or non-human primate blood, fluids, or tissue gives you the right to prompt medical evaluation and treatment with a qualified physician familiar with evaluations and treatment protocols as recommended by the Centers for Disease Control and Prevention. These services will be provided to you at no cost. **See Appendix W for HSC student procedures.**

What to do following an exposure

After any direct exposure to BBP through a needlestick, **immediately wash the affected area with soap and water and NOTIFY YOUR SUPERVISOR. For splashes with potential bloodborne pathogens, rinse affected area for 15 minutes.**

A. During Business Hours

University Park Campus	**Health Science Campus**
Students and employees should go to: Student Health Center 849 W. 34th St. (1st floor) Los Angeles, CA 90007 (213) 740-6205 - or as directed by Workers' Compensation	Students should go to: Eric Cohen Student Health Center 1510 San Pablo St. Suite 104 Los Angeles, Ca 90033 Tel: 323-442-5631 - or as directed by Workers' Compensation

<u>After Hours</u>

Employees should go to one of the following medical facilities. Employees must notify their supervisor of any injury or illness the following day or as soon as possible. The supervisor should notify Workers' Compensation/Laboratory Safety by phone and then complete and forward the proper forms.

White Memorial Hospital **1720 Cesar E. Chavez Ave.** **Los Angeles, CA 90033** **(323) 268-5000**	**Good Samaritan Hospital** **1225 Wilshire Blvd.** **Los Angeles, CA 90017** **(213) 977-2121**

Emergency Room Services are 24 hours per day; 7 days a week

These providers follow a protocol that is designed to provide the individual with the most appropriate medical procedures, consultation and supportive therapy.

The exposed employee or student will be provided with a written opinion that will include:

- HBV vaccination status and recommendation
- Results of the post-exposure evaluation and follow-up
- Discussion of any medical conditions resulting from exposure to blood or other potentially infectious materials which requires further evaluation or treatment
- All other findings or diagnoses will remain confidential and will not be included in the
- written report.

Exposure to animal bites and scratches

It is important to immediately report all bite wounds and scratches to your supervisor. Wounds must be cleansed immediately in your work area. Your supervisor will give you instructions for the proper cleaning of wounds. **After you have cleansed the wound, go immediately to one of the designated healthcare facilities or as directed by USC Workers' Compensation. If it is after hours, follow the directions listed above.** Medical information will not be discussed or revealed to supervisors, personnel representatives, or other health care professionals who do not need the information.

RECORD KEEPING [5193(h)]

The Principal Investigator/Supervisor must maintain all training records as discussed above for at least three years and provide record keeping for advising staff of the offer of the Hepatitis B vaccination. The medical provider maintains all medical records related to the provision of clinical services for thirty years. To access these records call the provider directly.

BBPECP APPENDIX 1
Exposure Determination

PI/SUPERVISOR:_____
DATE:_____
List of faculty, staff and students who have been determined to be at risk for exposure to bloodborne pathogens or other potentially infectious materials:

NAME	JOB TITLE	TRAINING DATE(S) INITIAL/ANNUAL	HEPATITIS B VACCINE	OFFER DATE

BBPECP APPENDIX 2
UNIVERSITY OF SOUTHERN CALIFORINA
K. HEPATITIS B VACCINATION AGREEMENT/ REFUSAL FORM

The hepatitis B vaccination is provided free of charge to USC employees who are exposed to human material including blood, blood products, body fluids, tissues, cell lines, or other potentially infectious material (OPIM) in the course of conducting their job responsibilities.

Federal regulations require that employers notify employees who are "at risk" that they have the right to be vaccinated. Although vaccination is optional, employers are required to confirm that they have been notified of this right.

The vaccination series is provided through the clinics listed below. You must make an appointment to receive services.

USC Department of Family Medicine
Health Care Consultation Center
1510 San Pablo St.
(323) 422-5807

USC Department of Internal Medicine
Health Care Consultation Center II
1520 San Pablo St.
(323) 442-5100

Student Health Services
849 W. 34th St.
(213) 740-9355

Please check one of the following:

☐ I am a student and understand that the USC Hepatitis B Program cannot provide the vaccine for me. I have been advised to seek assistance through Student Health Services or my own medical insurance provider.

☐ I accept the offer of the hepatitis B vaccination. I understand that it will be provided at no charge to me and that it is comprised of a series of three inoculations.

☐ I have previously completed the hepatitis B vaccination series and can show laboratory confirmation of immunity.

☐ I accept the offer of a hepatitis B antibody titer to check my immune status.

☐ I understand that due to my occupational exposure to blood or other potentially infectious material, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the hepatitis B vaccine at no charge. However, I decline the hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If I continue to have occupational exposure to blood or OPIM and wish to be vaccinated with hepatitis B vaccine in the future, I can receive the vaccination at no charge.

Additional Attestations

I understand that my acceptance or refusal to be vaccinated does not affect my USC health benefits or employment status.

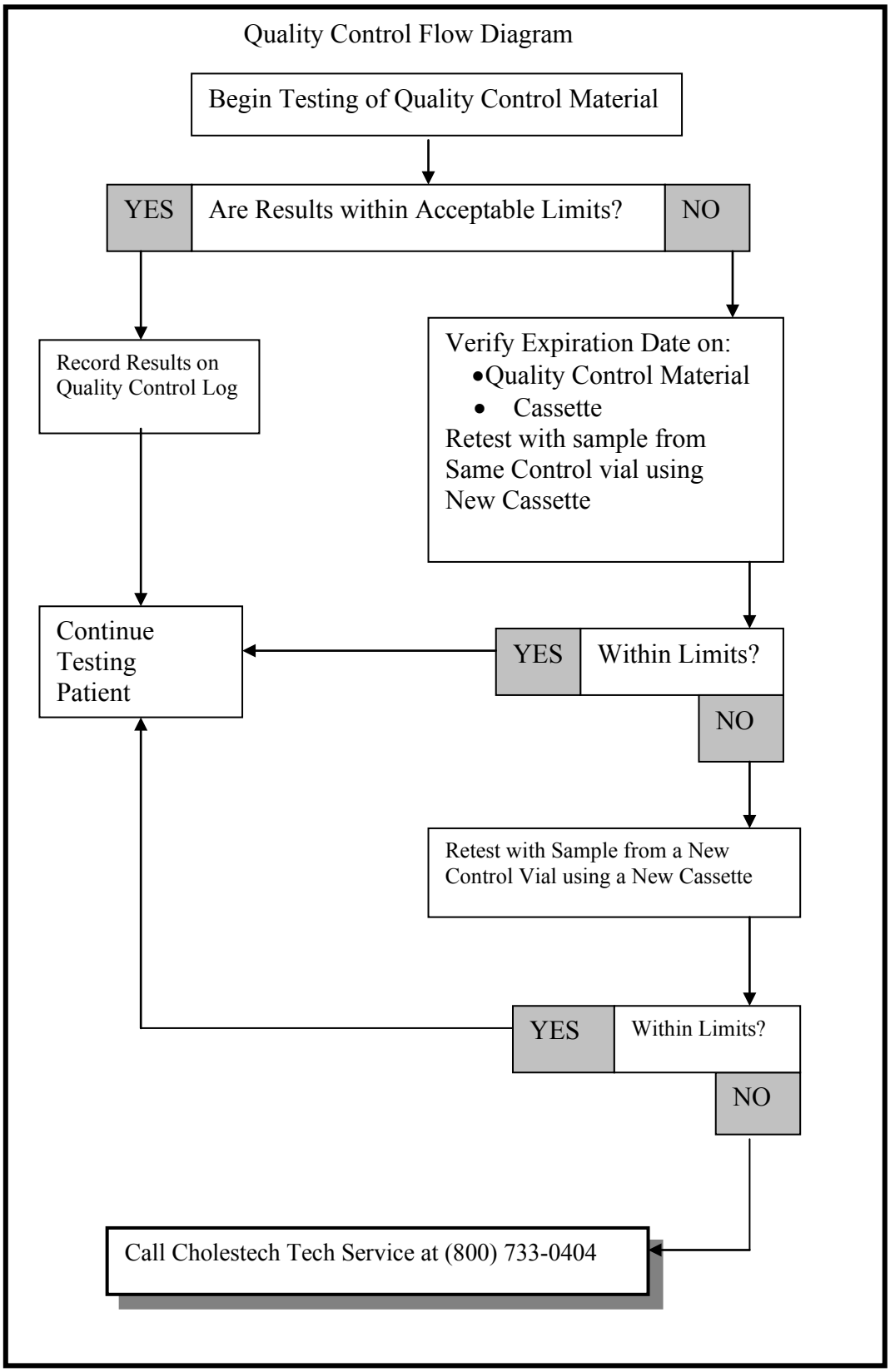
I recognize that I will be required to follow established safety procedures regardless of my vaccination status.

I understand that the University of Southern California is not liable for pre-existing infections that any employee has at the time of his or her employment with the University.

I understand that I also have the right to be tested for HIV if I am exposed to blood or bodily fluids. However, the HIV test will be conducted separately only upon my request, and not as part of the hepatitis B screening process.

Employee Name:	Employee Identification Number:	
Employee Signature:	Telephone:	
Email:	Date:	
Authorized by:	Signature:	Date:
BILL TO: HEPATITIS B PROGRAM Laboratory Safety, 1540 Alcazar St., CHP 148 Los Angeles, CA 90033-9005 (323) 442-2200		

APPENDIX D


Quality Control Flow Diagram
Begin Testing of Quality Control Material
YES
Are Results within Acceptable Limits?
NO
Record Results on Quality Control Log
Verify Expiration Date on:
•Quality Control Material
• Cassette
Retest with sample from Same Control vial using New Cassette
Continue Testing Patient
YES
Within Limits?
NO
Retest with Sample from a New Control Vial using a New Cassette
YES
Within Limits?
NO
Call Cholestech Tech Service at (800) 733-0404

APPENDIX E:
Optics Check Log

Cholestech LDX Serial #:_____ Acceptable Range: _____

Optics Check Cassette Lot #:_____ Expiration Date: _____

Date	Results				Performed By	Accept	Reject	Comments
	Ch.1	Ch.2	Ch.3	Ch.4				

APPENDIX F
Cholestech LDX
Quality Control Log

Control Range: TRG:_____

Cholestech LDX S/N:_____ TC:_____

Control Lot:_____ GLU:_____

Expiration Date: _____ HDL:_____

Control Level: _____ ALT:_____

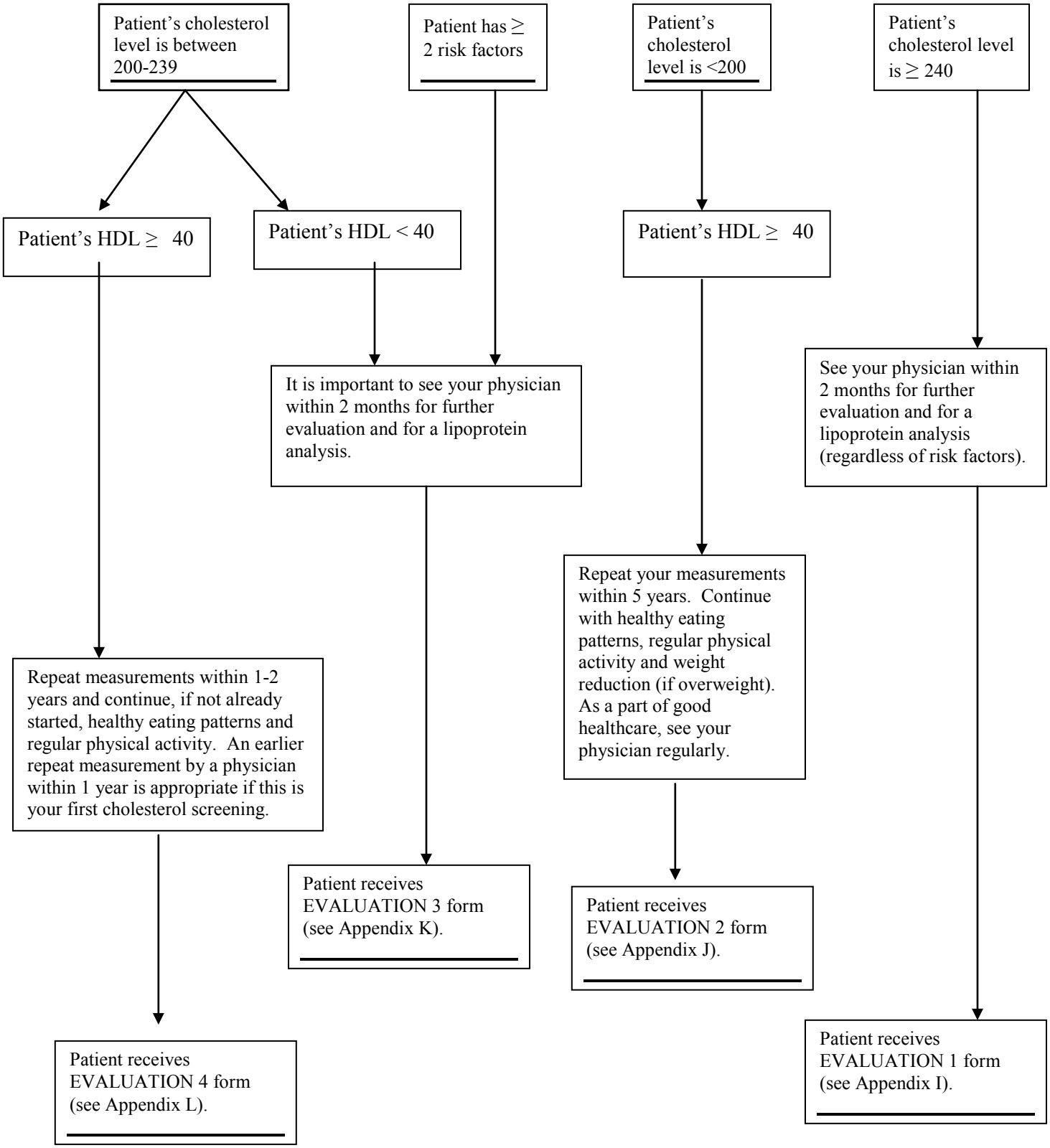
Date	Cassette Lot #	Control Expiration Date (opened)	Value	Accept	Reject	Operator	Comments Action taken

APPENDIX G
Cholestech LDX
Patient Result Log

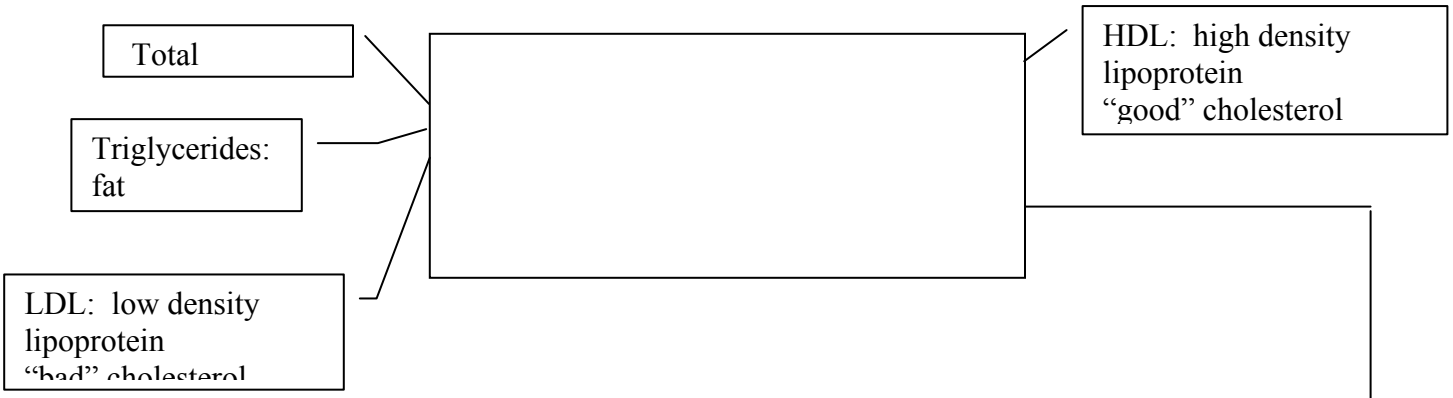
Cassette Lot #:_____Expiration Date:_____ LDX Serial #:_____

Date	Operator	Patient Name	Patient ID	TRG	TC	GLU	HDL	LDL	TC/HDL	ALT	ACTION TAKEN

APPENDIX H – RISK ASSESSMENT ALGORITHM


Patient's cholesterol level is between 200-239
Patient has ≥ 2 risk factors
Patient's cholesterol level is <200
Patient's cholesterol level is ≥ 240
Patient's HDL ≥ 40
Patient's HDL < 40
Patient's HDL ≥ 40
It is important to see your physician within 2 months for further evaluation and for a lipoprotein analysis.
See your physician within 2 months for further evaluation and for a lipoprotein analysis (regardless of risk factors).
Repeat your measurements within 5 years. Continue with healthy eating patterns, regular physical activity and weight reduction (if overweight). As a part of good healthcare, see your physician regularly.
Repeat measurements within 1-2 years and continue, if not already started, healthy eating patterns and regular physical activity. An earlier repeat measurement by a physician within 1 year is appropriate if this is your first cholesterol screening.
Patient receives EVALUATION 3 form (see Appendix K).
Patient receives EVALUATION 2 form (see Appendix J).
Patient receives EVALUATION 4 form (see Appendix L).
Patient receives EVALUATION 1 form (see Appendix I).

APPENDIX I – EVALUATION 1
Patient Cholesterol Level Evaluation



Name: Age: Sex:

What does my cholesterol level mean?

Total Blood Cholesterol Level _____
- Desirable: <200 mg/dl
- Borderline: 200-239 mg/dl
- High risk: ≥ 240 mg/dl

HDL- Cholesterol Level _____
- Desirable: ≥ 40 mg/dl
- Risk: <40 mg/dl

LDL-Cholesterol Level _____
- Desirable: <100 mg/dl
- Borderline: 130-159 mg/dl
- High risk: ≥ 160 mg/dl

Triglyceride (TG) Level _____
- Normal: <150 mg/dl
- Borderline High: 150-199 mg/dl
- High: 200-499 mg/dl
- Very High: ≥ 500 mg/dl

What are my risk factors?

- ❑ Male age ≥ 45 years or Female age ≥ 55 years
- ❑ Family history of premature coronary heart disease
- ❑ HDL level <40mg/dL
- ❑ Smoking
- ❑ Hypertension

Negative risk factor:

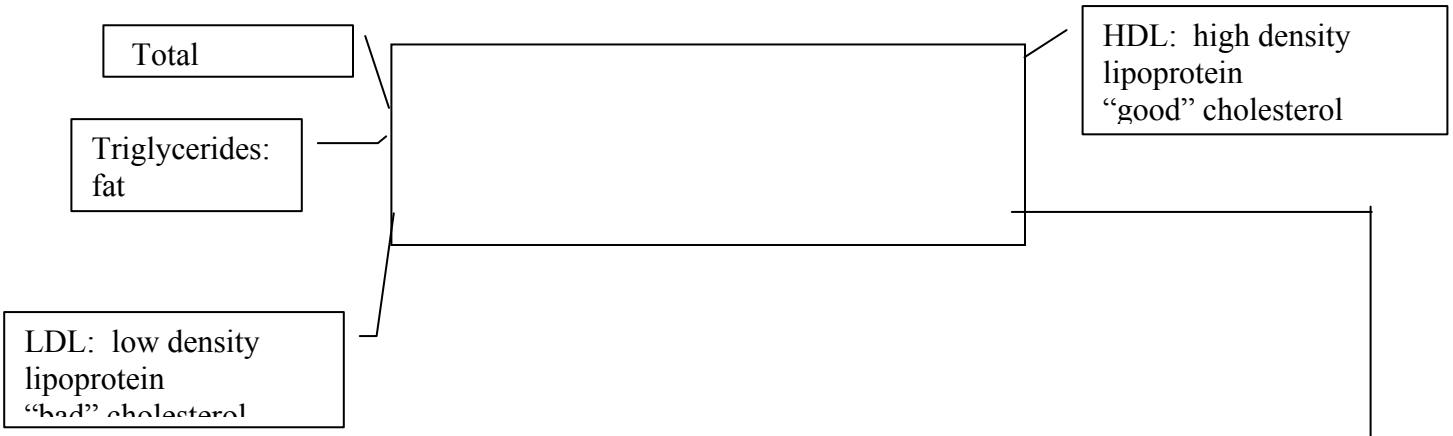
- ❑ HDL level > 60mg/dL

Risk Factors: _____

What do I need to do now?

See your physician within 2 months for further evaluation and for a lipoprotein analysis (regardless of risk factors).

APPENDIX J – EVALUATION 2
Patient Cholesterol Level Evaluation



Name: Age: Sex:

What does my cholesterol level mean?

Total Blood Cholesterol Level _____
- Desirable: <200 mg/dl
- Borderline: 200-239 mg/dl
- High risk: ≥240 mg/dl

HDL- Cholesterol Level _____
- Desirable: ≥40 mg/dl
- Risk: <40 mg/dl

LDL-Cholesterol Level _____
- Desirable: <100 mg/dl
- Borderline: 130-159 mg/dl
- High risk: ≥160 mg/dl

Triglyceride (TG) Level _____
- Normal: <150 mg/dl
- Borderline High: 150-199 mg/dl
- High: 200-499 mg/dl
- Very High: ≥ 500 mg/dl

What are my risk factors?

- ❑ Male age ≥45 years or Female age ≥55 years
- ❑ Family history of premature coronary heart disease
- ❑ HDL level <40mg/dL
- ❑ Smoking
- ❑ Hypertension

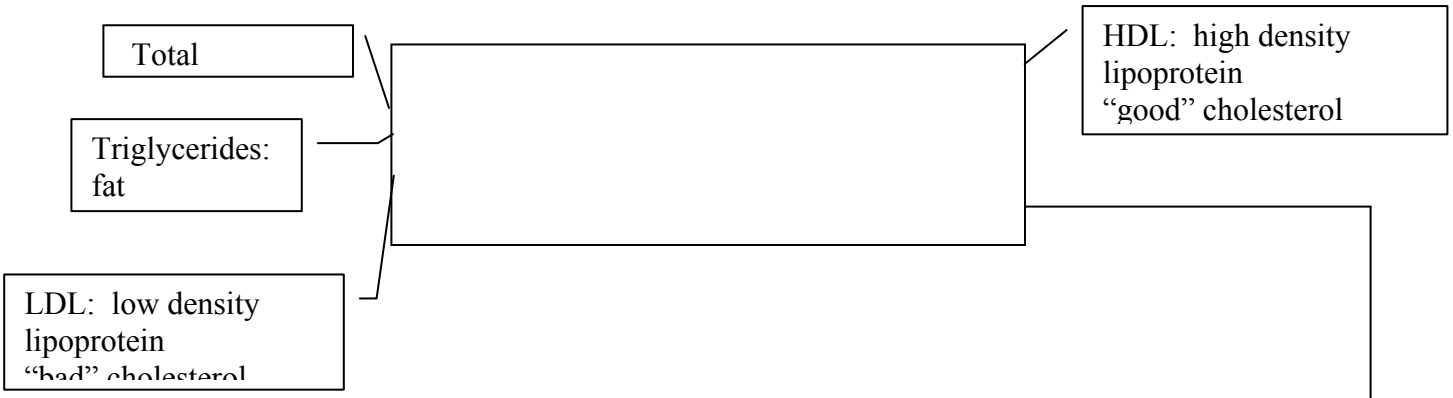
Negative risk factor:

- ❑ HDL level >60mg/dL
- ❑ Risk Factors: _____

What do I need to do now?

Your total cholesterol level is <200 and your HDL is ≥40.
Repeat your measurements within 5 years. Continue with healthy eating patterns, regular physical activity and weight reduction (if overweight).
As a part of good healthcare, see your physician regularly.

APPENDIX K – EVALUATION 3
Patient Cholesterol Level Evaluation



Name: Age: Sex:

What does my cholesterol level mean?

Total Blood Cholesterol Level _____
- Desirable: <200 mg/dl
- Borderline: 200-239 mg/dl
- High risk: ≥240 mg/dl

HDL- Cholesterol Level _____
- Desirable: ≥40 mg/dl
- Risk: <40 mg/dl

LDL-Cholesterol Level _____
- Desirable: <100 mg/dl
- Borderline: 130-159 mg/dl
- High risk: ≥160 mg/dl

Triglyceride (TG) Level _____
- Normal: <150 mg/dl
- Borderline High: 150-199mg/dl
- High: 200-499 mg/dl
- Very High: ≥ 500 mg/dl

What are my risk factors?

- ❑ Male age ≥45 years or Female age ≥55 years
- ❑ Family history of premature coronary heart disease
- ❑ HDL level <40mg/dL
- ❑ Smoking
- ❑ Hypertension

Negative risk factor:

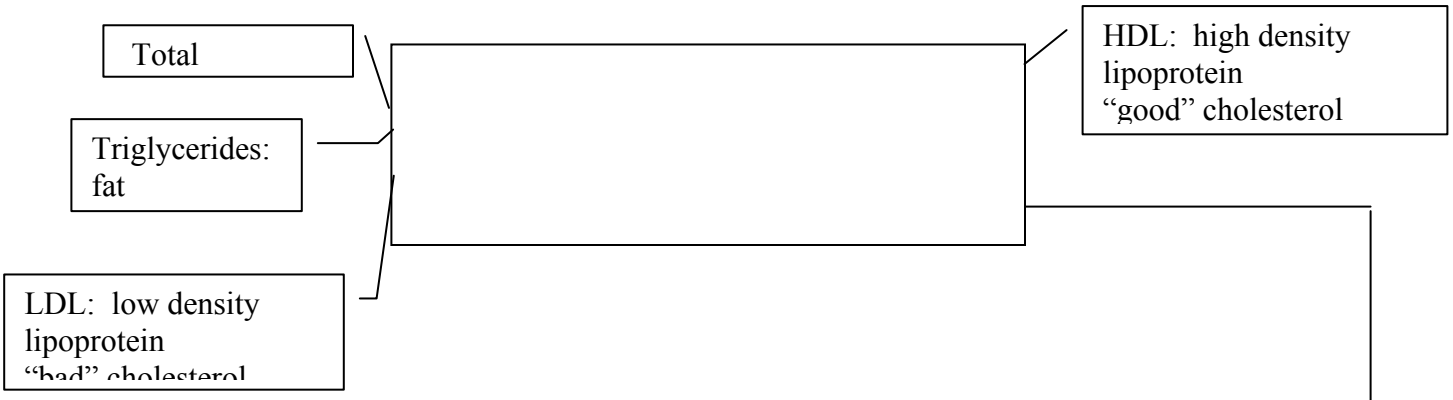
- ❑ HDL level >60mg/dL

Risk Factors: _____

What do I need to do now?

Your cholesterol level is between 200-239 mg/dl and your HDL <40 or ≥2 risk factors. It is important to see your physician within 2 months for further evaluation and for a lipoprotein analysis.

APPENDIX L – EVALUATION 4
Patient Cholesterol Level Evaluation



Name: Age: Sex:

What does my cholesterol level mean?

Total Blood Cholesterol Level _____
- Desirable: <200 mg/dl
- Borderline: 200-239 mg/dl
- High risk: ≥240 mg/dl

HDL- Cholesterol Level _____
- Desirable: ≥40 mg/dl
- Risk: <40 mg/dl

LDL-Cholesterol Level _____
- Desirable: <100 mg/dl
- Borderline: 130-159 mg/dl
- High risk: ≥160 mg/dl

Triglyceride (TG) Level _____
- Normal: <150 mg/dl
- Borderline High: 150-199 mg/dl
- High: 200-499 mg/dl
- Very High: ≥ 500 mg/dl

What are my risk factors?

- ❑ Male age ≥45 years or Female age ≥55 years
- ❑ Family history of premature coronary heart disease
- ❑ HDL level <40mg/dL
- ❑ Smoking
- ❑ Hypertension

Negative risk factor:

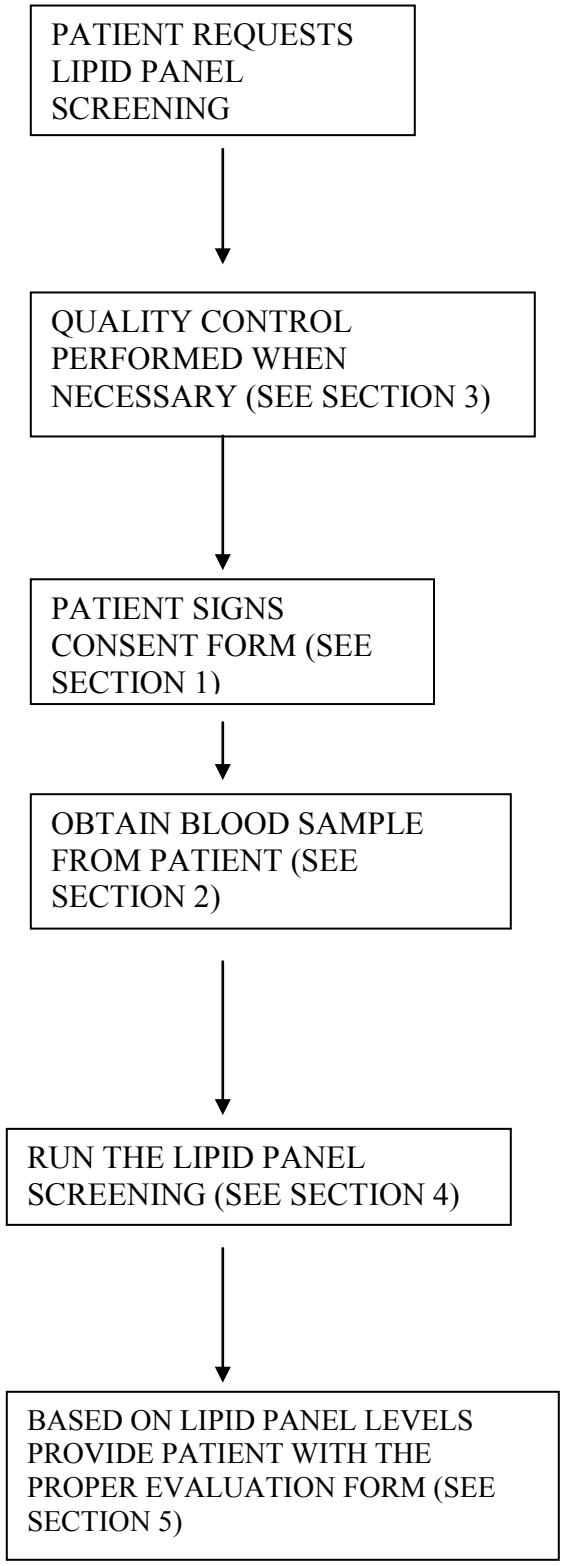
- ❑ HDL level >60mg/dL

Risk Factors: _____

What do I need to do now?

Your cholesterol level is between 200-239 mg/dl and your HDL is ≥40 with <2 risk factors. Repeat measurements within 1-2 years and continue, if not already started, healthy eating patterns and regular physical activity. An earlier repeat measurement by a physician within 1 year is appropriate if this is your first cholesterol screening.

APPENDIX M – NON-DIAGNOSTIC LIPID PANEL SCREENING FLOW CHART


PATIENT REQUESTS LIPID PANEL SCREENING
QUALITY CONTROL PERFORMED WHEN NECESSARY (SEE SECTION 3)
PATIENT SIGNS CONSENT FORM (SEE SECTION 1)
OBTAIN BLOOD SAMPLE FROM PATIENT (SEE SECTION 2)
RUN THE LIPID PANEL SCREENING (SEE SECTION 4)
BASED ON LIPID PANEL LEVELS PROVIDE PATIENT WITH THE PROPER EVALUATION FORM (SEE SECTION 5)

APPENDIX N – TROUBLESHOOTING

CARDIOCHEK ANALYZER

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
Desired language is not displayed.	Language has been set incorrectly.	Turn analyzer OFF. See Section IV, Set Up - How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section IV, Set Up to set the correct date and time.
FAILED is displayed during a Check Strip test.	Analyzer needs to be cleaned. Check Strip is dirty or damaged.	Wipe the Test Strip Insert Opening with a clean, damp and lint-free cloth. Use spare Check Strip. If Check Strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows and away from direct lamp light.
MEMO ERR	MEMo Chip is defective.	Use another MEMo Chip from the same lot
TEST ERR	Insufficient sample has been added to Test Strip.	Test again with a new Test Strip and make sure the correct volume of sample is used.
SET TIME AND DATE	Analyzer is new or language option has not been set.	Follow User Guide instructions to set language.
TEST NOT ALLOWED	Test selected by MEMo Chip installed cannot be run on your analyzer.	Check MEMo Chip and make sure that the correct MEMo Chip is inserted. Call Customer Service.
LOW TEMP	Analyzer is below acceptable operating temperature.	Move to warmer environment and test after analyzer reaches proper temperature.
HI TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
INSTALL MEMO CHIP	MEMo Chip is not properly inserted or is defective.	Insert same or new MEMo Chip properly.
MEMO CHIP ERROR	MEMo Chip is defective.	Use another MEMo Chip from same lot of product.
EXPIRED LOT	Test Strips are expired, wrong MEMo Chip is inserted or analyzer Date is not set properly.	Check Test Strip expiration date and make sure correct MEMo Chip is inserted. Check analyzer Date setting – follow User Guide instructions.
CHANGE BATTERY	Batteries need to be replaced.	Replace both batteries with new high quality AAA batteries. (The analyzer will not run tests until batteries are replaced.)
TEST ABORTED	Test Strip was not properly inserted or was removed before test was complete.	Test again with fresh Test Strip.
TRIGS TOO HIGH LDL N/A	Lipid Panel triglycerides test result was 400 mg/dL (4.52 mmol/L) or greater.	No action needed. LDL will not be calculated on samples with triglycerides of 400 mg/dL (4.52 mmol/L) or greater.
PRINT ERROR	Print function has been interrupted.	Print result in MEMORY or test again.
Results will not print.	Communication Cable was improperly connected. Printer cover is not closed properly. (Printer indicator light is red.) Labels / paper were not loaded in the printer.	Check all connections. Reprint test results stored in memory. Close printer cover correctly, ensuring that the Printer indicator light is green. Reprint test results stored in memory. See Section IV, Set Up for instructions on how to load labels/paper into the printer.

High or low results that are incorrect may have serious medical consequences. If the result reads > (greater than) or < (less than) or results are not as expected, always repeat the test correctly with a new unused Test Strip. If a test result is displayed that is not expected, consult the following table.

PROBLEM	PROBABLE CAUSE	SOLUTION
Results are not as expected.	Strips improperly stored.	Repeat test, using a different vial of strips. Run controls, confirm that results are in range.
	Batteries are defective.	Change batteries.
	The analyzer was improperly stored.	Make sure analyzer was not exposed to high or low temperatures or humidity and repeat test.
	Test Strip Insert Opening is dirty.	Clean the Test Strip Insert Opening.
	MEMo Chip and Test Strips are not the same lot number.	Use MEMo Chip and Test Strips with the same lot number.
A displayed result reads < (less than) a value	Result is below the measuring range of the test.	If you or your patient have symptoms call healthcare professional immediately. Repeat the test. Run controls and confirm that controls are in range.
A displayed result reads > (greater than) a value.	Result is above the measuring range of the test.	If you or your patient have symptoms call healthcare professional immediately. Run test again. Run controls and confirm that controls are in range.
Display reads "_ _ _ _" or N/A	Result is not available due to a missing value from a calculation. Or a value is outside the measuring range.	Run test again. Run controls and confirm that controls are in range.

CHOLESTECH LDX SYSTEM

Error Message	Problem	Action to Take
Mag Read Error See User Manual	Unable to read magnetic stripe on the cassette	1. Wipe magnetic stripe with a soft tissue and restart test. If second test fails, repeat test using a new cassette. 2. Check cassette position, magnetic stripe must be on the right. 3. If message reappears, call Technical Service
	Run button pushed without cassette in drawer.	Place cassette in drawer before pushing Run
Tray Timeout See User Manual	The cassette is jammed in the tray.	
	The microprocessor is confused because the buttons were pressed too quickly.	Disconnect/Reconnect Analyzer from power supply. Repeat test with a new cassette. If message reappears, call Technical Service
Calibration Fail Call Tech Service	An electrical problem occurred, or the Analyzer lost its optical calibration information	Disconnect/Reconnect Analyzer from power supply. If message reappears, call Technical Service
Used Cassette	A previously used cassette has been placed in the Analyzer	Repeat test with a new cassette. Dispose of used cassette appropriately
	The cassette was placed incorrectly.	Repeat test with a new cassette. Call technical service if message reappears
	The cassette is malfunctioning	Repeat test with a new cassette
Data file empty	This is normal message which appears:	1. When the optics Check has been run and DATA is pushed. 2. A cassette has been run, the power supply has been unplugged from the LDX and DATA is pushed. 3. When an error message occurs, i.e. “Used Cassette”, and DATA is pushed
End of data info	This is a normal message which appears:	1. Framingham risk is off and DATA button is pushed twice after results appear. 2. Framingham risk is on and the STOP button is pushed when “Risk? – Run = yes, STOP + no” appears.
A/D Error	Internal hardware problem	Disconnect/Reconnect Analyzer from power supply. If message reappears call Technical Service.

***NOTE**: do not try to run a cassette if you have been troubleshooting a problem with it for more than 30 seconds. Evaporation of sample may cause inaccurate results.*

Error Message	Problem	Action to Take
Reaction Did Not Occur	Insufficient sample volume was applied to the cassette due to air bubbles or incompletely filled capillary tube or pipette.	1. Repeat test with a new cassette and new fingerstick sample. 2. Repeat test with a new pipette tip and cassette. Be sure pipette tip is firmly in place.
	Insufficient sample volume reached reaction pads due to high hematocrit or sample.	Repeat test with a new cassette and new fingerstick sample. If message reappears, test patient by alternate method
	Improper sample collection: sample clotted because it was left in the capillary tube too long	Repeat test with a new cassette and new fingerstick sample. Pay close attention to proper technique.
	Improper sample collection: Finger was milked to obtain sample, or capillary tube was filled too slowly.	Repeat test with a new cassette and new fingerstick sample. Pay close attention to proper technique.
	The cassette is malfunctioning	Repeat test with a new cassette
Low Battery	Internal battery voltage is too low	Call Technical Service. Internal battery is not user serviceable.
WARN 1	The analyzer is in an environment outside its proper temperature range.	
WARN 2	Cassette expiration date, month has been reached	Check calendar in the Analyzer to make sure it is set correctly. Check expiration date on cassette pouch or box.
WARN 3	There is a large difference between two readings that are used to calculate a mean value.	Repeat the test with anew cassette
WARN 7	Kinetic reaction for ALT was not linear	Repeat the test with anew cassette
Optics Test Fail See User Manual	A problem with the optical system of the analyzer or a faulty Optics Check Cassette.	Repeat optics check with another optics check cassette. If the message reappears, call Cholestech Technical Service. The Analyzer will now be deactivated
Too Much Light See User Manual	The analyzer is in an environment with excessively	Move the Analyzer to a location with less light. When light level

	bright light	is acceptable, it will again become operable.
Temp Too High See User Manual	The analyzer is in an environment outside its proper temperature range	Move the Analyzer to another location. When it reaches acceptable temperature, it will again become operable.
Selftest Fail	Analyzer has lost internal memory; temperature malfunction or hardware problem.	Disconnect/Reconnect Analyzer from power supply. If message reappears call Cholestech Technical Service.
Bad Checksum	Indicates a defective ROM pack.	Unplug the LDX. Remove ROM pack and install a ROM pack from an LDX which is functional. If the LDX is functional with thins ROM pack then the problem is the ROM pack and it will have to be replaced. Call Cholestech Technical Service.

NOTE: do not try to run a cassette if you have been troubleshooting a problem with it for more than 30 seconds. Evaporation of sample may cause inaccurate results.

APPENDIX O – DIABETES CONSENT FORM

USC School of Pharmacy

Patient's Name: _____
Today's Date: _____
Your Age:_____ Gender:_____ Height:_____ Weight:_____ Race:_____

1. Have you been diagnosed with diabetes? ____Yes ____No
   If YES, do not complete ADA Risk Assessment Form

2. Have you consumed food or liquid other than water in the past 8 hours? ____Yes ____No

3. Would you like us to contact your physician with the results of the assessment? ____Yes ____No

If **YES**, please provide physician information:
Physician's Name: _____
Daytime Phone: _____

I have read or have had explained the information provided about the diabetes screening I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of diabetes screening and ask that a finger stick be performed on me or on the person named above for whom I am authorized to make this request.

Patient Signature: _____

APPENDIX O – CHOLESTEROL CONSENT FORM

USC School of Pharmacy

Patient's Name: _____
Today's Date: _____
Your Age:_____ Gender:_____ Height:_____ Weight:_____ Race:_____

1. Have you been diagnosed with high cholesterol? ____Yes ____No
   If yes, do you take cholesterol lowering medications? ____Yes ____No

2. Have you consumed food or liquid other than water in the past 8 hours? ____Yes ____No

3. Would you like us to contact your physician with the results of the assessment? ____Yes ____No

If **YES**, please provide physician information:
Physician's Name: _____
Fax # : _____

I have read or have had explained the information provided about the cholesterol screening I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of cholesterol screening and ask that a finger stick be performed on me or on the person named above for whom I am authorized to make this request.

Patient Signature: _____

APPENDIX P – ADA RISK ASSESSMENT FORM

Diabetes Risk Test

Sixteen million Americans have Diabetes, and 1 out of 3 doesn't eve know it! Take this test to see if you are at risk for having diabetes. Diabetes is more common in African America, Hispanics, Native Americans, Asian Americans, and Pacific Islanders. If you are a member of one of these ethnic groups, you need to pay special attention to this test. To find out if you are at risk, circle the number of points next to each statement that is **true** for you. If a statement is not **true**, circle zero. Add your circled numbers to get a total score.

	YES	NO
1. My weight is equal to or above that listed in the chart?	5pts	0pts
2. I am under 65 years of age and I get little or no exercise during the usual day.	5pts	0pts
3. I am between 45 and 64 years of age.	5pts	0pts
4. I am 65 years or older.	9pts	0pts
5. I am a woman who has had a baby Weighing more than nine pounds at birth.	1pt	0pts
6. I have a sister or brother with diabetes.	1pt	0pts
7. I have a parent with diabetes.	1pt	0pts

Total Points: _____

Scoring 3-9 pts:
You are at low risk for having diabetes now. But don't just forget about it – especially if you are Hispanic/Latino, African American, American Indian, Asian American, or Pacific Islander. You may be at higher risk in the future. New guidelines recommend everyone age 45 and over consider being tested for the disease every 3 years. However, people at high risk should consider being tested at a younger age. Keep your risk low by losing weight if you are overweight, being active most days, and eating low fat meals that are high in fruits and vegetables, and whole grain foods.

Scoring 10 or more points:
You are at high risk for having diabetes. Only your health care provider can determine if you have diabetes. See your health care provider soon and find out for sure.

Height	Weight
Feet/inches Without shoes	Pounds Without clothing
4' 10"	129
4' 11"	133
5' 0"	138
5' 1"	143
5' 2"	147
5' 3"	152
5' 4"	157
5' 5"	162
5' 6"	167
5' 7"	172
5' 8"	177
5' 9"	182
5' 10"	188
5' 11"	193
6' 0"	199
6' 1"	204
6' 2"	210
6' 3"	216
6' 4"	221
If you weigh the same or more than the amount listed for your height, you may be at risk for diabetes. This chart is based on a measure called the Body Mass Index (BMI). The chart shows unhealthy weights for men and women age 35 or older at the listed heights. At-risk weights are lower for individuals under age 35.	

APPENDIX Q - PARTICIPANT ASSESSMENT FORM

PATIENT ASSESSMENT FORM
USC School of Pharmacy

NAME

DIABETES RISK SCORE

BLOOD GLUCOSE LEVEL

TYPE OF TEST	_____Fasting	_____Non-Fasting

ACTION PLAN

APPENDIX R – INSTRUCTIONS ON USING THE GLUCOMETER

Attach manual for CLIA Waived Glucometer

APPENDIX S – Limited Quantity Medical Waste Transporter and Small Quantity Medical Waster Generator Certificate

STATE OF CALIFORNIA
Department of Public Health
Medical Waste Management Program

California Department of PublicHealth

USC Pharmacy

Registration No.
19-11323

In the county of
Los Angeles
is registered as a

Treatment Permit No.
None

SMALL QUANTITY MEDICAL WASTE GENERATOR

Expiration Date
December 16, 2010

The facility named herein is registered pursuant to the provisions of the Medical Waste Management Act, Division 104, Part 14, Chapter 5 of the California Health and Safety Code, and shall be subject to all applicable provisions of this law. This permit is not transferable.

Date Issued: 01/06/2010

Chief, Waste Management Section

STATE OF CALIFORNIA
Department of Public Health
Medical Waste Management
Program

PublicHealth

USC Pharmacy

Registration No.
19-1436

in the county of
Los Angeles
is registered as a

Treatment Permit No.
None

LIMITED QUANTITY MEDICAL WASTE TRANSPORTER

Expiration Date
December 16, 2010

The facility named herein is registered pursuant to the provisions of the Medical Waste Management Act, Division 104, Part 14, Chapter 5 of the California Health and Safety Code, and shall be subject to all applicable provisions of this law. This certificate is not transferable.

Date Issued: 2/11/2010

Chief, Waste Management Section

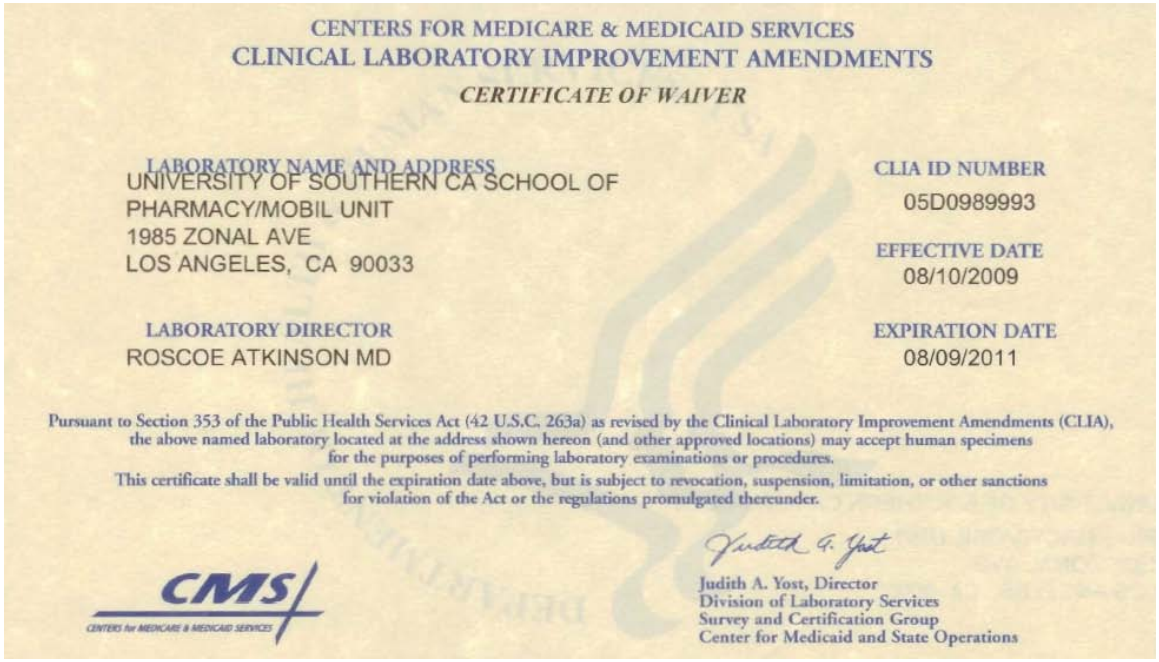
APPENDIX T – Completion of Lipid Testing Training

CHOLESTECH AND FINGERSTICK TRAINING

Date: _____ **Location: USC School of Pharmacy**

Name	Trainer Name

APPENDIX U. CLIA Certificate



CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS
UNIVERSITY OF SOUTHERN CA SCHOOL OF
PHARMACY/MOBIL UNIT
1985 ZONAL AVE
LOS ANGELES, CA 90033

CLIA ID NUMBER
05D0989993

EFFECTIVE DATE
08/10/2009

LABORATORY DIRECTOR
ROSCOE ATKINSON MD

EXPIRATION DATE
08/09/2011

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

APPENDIX V. Non-Diagnostic General Health Assessment (LA County)

Per event

USC Bloodborne Pathogen
Exposure Protocol

Initial Visit Baseline Data

Patient Information (exposed person)

Name_____DOB_____

_____

Institution of Employment/Enrollment_____

__

Medical History

Current_____

Past_____

Kidney Dis._____ Liver Dis._____ Heme Dis._____

LMP_____ Pregnancy (wks of gestation)_____ Breast feeding_____

Medications

Current_____

Allergies_____

Pre-existing infection (circle)

HIV infected: Yes/No HBV infected: Yes/No HCV infected: Yes/No

Susceptibility

Hepatitis B vaccine series completed? Yes/No HBV sAb titer_____

Exposure Information

Date & Time of Exposure_____

Location (hospital/clinic) of Exposure_____

Type of Exposure (needlestick, scalpel, splash, etc.)_____

How Exposure Occurred (suturing,etc.)_____

Type of Substance Exposed to (blood, CSF, etc)_____

Area exposed (finger, eyes, etc.)_____

For Percutaneous exposure: depth of injury and whether fluid injected_____

For Mucocutaneous Exposure: volume of material, duration of contact, & condition of skin/mucosa (abraded, chapped, intact, etc.)_____

Exposure Source

Name_____DOB_____

_____

Location (facility& room #)_____

Medical Problems_____

_____

Infection Status (circle)

HIV: Pos/Neg **HBV sAg**: Pos/Neg **HBV eAg**: Pos/Neg **HCV Ab**: Pos/Neg

If known HIV +: HIV disease stage or symptoms, past & current antiretroviral therapy, current DC4 & viral load:

_____

_____

If unknown HIV status: HIV risk factors in patient, or prevalence in clinic population (for unknown source, e.g. sharps box)

_____

_____

Patient Name_____DOB_____MRN_____

_____

School _____Grad Year_____

USC Bloodborne Pathogen
Exposure Protocol

Initial Visit Assessment and Plan

1. **HIV** Post Exposure Prophylaxis (PEP)

   a. **Circle** recommended PEP regimen based on Exposure type and source patient status

Exposure Type		Infection Status of Source				
		HIV+ Low Titer	HIV + High Titer	Unknown HIV	Unknown Patient	HIV Negative
Percutaneous	Solid/ Superficial	2 Drug Regimen	3 Drug Regimen	2 Drugs PRN Risks	2 Drugs PRN Risks	No PEP Indicated
	Hollow/ Deep/ Bloody	3 drug Regimen	3 drug Regimen	2 Drugs PRN Risks	2 Drugs PRN Risks	No PEP Indicated
Mucocutaneous	Small Volume	2 Drug Regimen	2 Drug Regimen	2 Drugs PRN Risks	2 Drugs PRN Risks	No PEP Indicated
	Large Volume	2 Drug Regimen	3 drug Regimen	2 Drugs PRN Risks	2 Drugs PRN Risks	No PEP Indicated

   b. **Circle** Prescribed HIV PEP Regimen
   (Note: PEP regimen is for 4 weeks)

Medication Regimens	Dosage	Side Effects & Comments
2 Drug		
Combivir (AZT-3TC)	300/150mg 1 PO BID	Nausea, HA, Insomnia, fatigue, Inc. LFT, Dec. Hgb, Dec. WBC, Dec. Plt, peripheral neuropathy, rare pancreatitis
3 Drug		
Combivir Plus: Nelfinavir (viracept)	5 PO BID, with food	Diarrhea (PRN Tx), P450 drug interactions

or Indinavir (Crixivan)	400mg 2 PO Q 8hrs on Empty Stomach or with Nonfat snack	Nephrolithiasis (must drink ≥1.5 *l* H2O daily, asymptomatic inc. bilirubin, rare hemolytic anemia, P450 drug interaction

2. **Hepatitis B** PEP- ***Circle/Fill In***

HBIG (0.06 ml/kg IM)
Date/s:_____
HBV Vaccine Booster
Date:_____

HBV Vaccine Serie:	Date Due (Scheduled)	Date Done/ Initials	Lot Number/
#1	_____	_____/_____/_____	
#2	_____	_____/_____/_____	
#3	_____	_____/_____/_____	

USC Bloodborne Pathogen
Exposure Protocol

Exposed Patient Testing

Test	Date Ordered/Initials	Results/Date reviewed	Indicated Follow-Up
Baseline labs			
HIV antibody			
HBV sAB Titer			
HCV antibody			
ALT			
CMP			
CBC w/ Diff			
RPR			
Pregnancy test			
2 week Labs (if on HIV PEP)			
CMP			
CBC w/ Diff			
4 week Labs (if on HIV PEP)			
CMP			
CBC w/ Diff			
6 week Labs			
HIV antibody			
HBV sAB Titer			
HCV RNA			
ALT			
RPR			
3 Month Labs			
HIV antibody			
HCV antibody			
HCV RNA			
ALT			
6 Month Labs			
HIV antibody			
HBV sAB Titer			

HCV RNA			
ALT			
12 Month Labs			
HIV antibody			

Notes:

1. HBV sAB titer- if not done in past, or results not known
2. Metabolic panel, with liver function test, and CBC w/ Diff- if taking HIV PEP
3. Syphilis testing- if indicated by source patient risk status
4. Pregnancy test- if indicated by exposed patient risk status
5. Repeat HBV sAB titer- if HBV vaccine booster or series has been given
6. 6 week HCV RNA- if early diagnostic evaluation indicated by symptoms of history
7. HCV RNA- confirmatory test to be ordered when HCV antibody positive, or HCV symptoms with negative antibody
8. ALT- baseline and subsequent screen for HCV (antibody sometimes negative)
9. Extended HIV testing- indicated when concurrent HCV sero-conversion, or if possible delayed immune response

USC Bloodborne Pathogen
Exposure Protocol

Information Sheet for Health Care Worker/ "Exposed Person"

(*Tear off remaining 3 pages and give to Exposed Person*)

Things that you, the "exposed person" need to know and/or do:

1. Get testing and risk assessment done on the source patient you were exposd to:
   - Give attached "Information Sheet for Attending Physician" sheet to the Patients doctor.

2. Return for follow-up evaluation, testing, counseling and Treatment
   - Fill in the following dates at your initial visit:
     - 2 weeks after exposure (*If* taking HIV Medication)
       _____
     - 4 weeks after exposure (*If* so directed)
       _____
     - 6 weeks after exposure (*For Everyone*- For testing)
       _____
     - 3 months after exposure (*For Everyone*- For testing)
       _____
     - 6 months after exposure (*For Everyone*- For testing)
       _____
     - Additional Appointment (as indicated)
       _____
     - Additional Appointment (as indicated)
       _____
     - Additional Appointment (as indicated)
       _____

3. Take all of your prescribed medications as directed. This is especially critical for HIV drugs!

4. Report and/or come in for evaluation of any side effects of therapy and/or infection:
   - Common HIV therapy side effects
     nausea, H/A, tiredness, difficulty sleeping, back pain/kidney stones, diarrhea

   - Common HIV symptoms:
     fever, rash, swollen lymph nodes, sore throat, aching, ect. (a bad "flu")

- Common Hepatitis symptoms:
  fever, nausea, vomiting, abdominal pain, yellow skin and eyes, tiredness

5. Call or come in to the Eric Cohen Student Health Center for any problems or questions!

Numbers to Call

Eric Cohen Student Health Center	323-442-5631
Student Health Nurse on Call	323-442-5631
LAC-USC HIV/AIDS Clinic	323-343-8255
National Post-Exposure Hotline	888-448-4911
Other	911

USC Bloodborne Pathogen
Exposure Protocol

Information Sheet for Attending Physician of "Source Patient"

Dear Doctor,

We need your assistance for a fellow healthcare worker who has sustained an occupational bloodborne exposure with a patient at your facility/ under your care as detailed below.

- Date and time of exposure:
  _____
- Facility and room location of exposure
  _____
- Source of exposure (e.g. needlestick, splash)
  _____
- Your Patients
  - Name
    _____
  - Date of Birth
    _____
  - Medical Record Number
    _____
- An unknown patient (e.g. sharps containter)
  _____

In order to assist in the post-exposure care of the health care worker, we need for you to **1. order lab tests, 2. obtain risk information, and 3. have the results faxed to us ASAP,** as detailed below. Your assistance in this matter is greatly appreciated!

If exposure was to an "unknown patient", please skip to 2C on the next page

1. **Order Lab Tests** (or provide us known results): (**note:** This is voluntary and must be with your patients consent)

a) HIV (antibodies by EIA) Date ordered/results
_____

b) HBV (HBxAg; HBeAg if known sAg+) Date ordered/results _____

c) HCV (anti- HCV) Date ordered/results _____

2. Obtain Risk Information (If results of HIV, HBV, & HCV are already known, skip to 2B)

a) For exposure to your patient: Please indicate below the presence or absence of risk factors. Note that your patient's cooperation in providing this information is voluntary under law. If your patient refuses to cooperate, please indicate so here: (circle) **Patient Refuses**

- Receipt of blood product transfusion or organ tissue transplantation

Yes No

If yes, Date, Type and Place_____

- Use of injection drugs with sharing of needles, "works" or drugs

Yes No

If yes, Date, Type and Place_____

USC Bloodborne Pathogen
Exposure Protocol

- Sexual exposure- please note the following risk factors
  - Sex with many partners (i.e. not both virgins)
    Yes No
  - Sex with exchange of blood, semen or vaginal fluids(i.e., no barriers used or barrier failed, including penial-vaginal, anal and oral-genital intercourse)
    (Circle applicable)

    Yes No
  - Sex under the influence of any drugs or alcohol (where safe sex may not have been adhered to)
    Yes No
  - Prior unsafe sex as evidenced by history of STD's or unplanned Pregnancy
    Yes No
  - Sex with anyone having any of the above risk factors
    Yes No
  - If there are any other circumstances of risks that we should be aware of, please indicate them here._____
    _

b) If your patient is known to be HIV+, please provide the following HIV disease details.

- HIV disease stage or symptoms
  _____
- Past and current antiretroviral therapy
  _____
- Current CD4 and Viral Load
  _____
- Other things that should be known about the patient
  _____

c) For Exposure to unknown patient:

- Are there any known/ likely HIV+, HBV+ or HCV patients treated at this site? **Yes No**

If **Yes**, pelase estimate the approximate percentage of the total patients seen which are known or likely to be so infected. (Write in the percentage) _____

- Are there any other contagious conditions to which the HCW may have been exposed to?

_____

Please indicate the best way to contact you for lab results or questions:

Your Name_____
Title_____
Contact Numbers (phone, fax, pager)_____
Address:_____

Please complete this form *As Soon As Possible* and send it to:

Eric Cohen Student Health Center
1510 San Pablo St. Suite 104
Los Angeles, Ca 90033
Tel: 323-442-5631
Fax: 323-442-6029

Thank you for your assistance!